A CLINICAL STUDY ON NEER KANA MAANTHAM (ACUTE NASO PHARYNGITIS) WITH THE EVALUATION OF SIDDHA DRUG OMA KUDINEER

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CERTIFICATE

This is to certify that the dissertation entitled "A CLINICAL STUDY ON NEER KANA MAANTHAM (ACUTE NASO PHARYNGITIS) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG OMA KUDINEER" is a bonafide work done by Dr.D.S.LAVANYA, Government Siddha Medical College,Chennai-600106 in partial fulfillment of University rules and regulations for the award of SIDDHA MARUTHUVA PERARIGNAR under my guidance and supervision during the academic year 2015-2017.

Name & Signature of the Guide

Name & Signature of the Head of the Department

Name & Signature of the Dean/Principal

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CONTENTS

INTRODUCTION

INTRODUCTION

Siddha medicine is a system of traditional medicine originating in ancient tamilakkam in South India. This system is believed to have originated several centuries ago or even since the beginning of the history of mankind. Lord Shiva is the first saint to describe about the siddha medicine to "***NANDHI DEVAR***"

And Nandi devar passed it to other saints. Agasthiyar is considered the first siddha and the guru of all siddhars.

According to the ancient siddha texts, a human body is made of several elements. It's a microscopic component of universe.

The elements that form a human body are earth (munn), fire (thee), water (neer), air (vayu) and space (akasam).

Additionally, there are three humors or doshas called the vata, pitta, and kapha.

It's all about balancing the three humors

- ***VAADHAM***
- ***PITTHAM***
- ***KABAM***

Under normal conditions the ratio between vaadham, pittham and kabam are 4:2:1 respectively

Which are induced by ***ARUSUVAI UNAVU***. They are

1. ***INIPPU***
2. ***PULIPPU***
3. ***UPPU***
4. ***KAIPPU***
5. ***KARPPU***
6. ***THUVARPPU***

Found in our meals daily. Also our body is formed by five elements.

It is said in the siddhar song '***DEGAM PANCHA POODAM'***

Siddha system of medicine not only cures the diseases but also increases the immunity system. In this system there is an unique method of treating pediatric groups. Since they are the pillars of upcoming centuries.

But nowadays there are no joint family system is most of the families so their children depend on medicines for smaller problems. They can be cured by siddha medicines without harming their body, unlike allopathic medicine for this disease causes drowsiness and many side effects. But using herbal medicine will increase the immune system of the body and hence prevents further infection to the body. Also, inappropriate use of antibiotics can lead to development of antibiotic resistance and can possibly lead to side effects, such as allergic reaction.

The ancient siddha medical system can handle diseases purely on herbs. The combinational blend of herbs acts in synergy to subside the infection with its own natural antibiotics.

The main reason for most of the people choosing ethic medicines like siddha for handling cold and cough is due to its simplicity and without side effects. The Indian medicine system of siddha handles cold and cough with simple spices at home or by easily available herbs and easily preparable at home.

The signs and symptoms of Neer kana Maantham mentioned in siddha paediatric book-bala vagadam may be correlated with acute naso pharyngitis in modern disease of classification .So I considered to evaluate a mixed herbal formulation **"Oma kudineer**" mentioned in balavagadam for the treatment of **Neer kana Maantham.**

AIM AND OBJECTIVE

AIM AND OBJECTIVE

AIM:

The aim of study is to evaluate the disease **NEER KANA MAANTHAM** [Acute Naso Pharyngitis] both clinically and experimentally with trial drug **OMA KUDINEER**.

OBJECTIVE:

- To review the literature of the disease Neer Kana Maantham in Siddha and Modern Medicine aspect.
- To compare the etiology, incidence, clinical features, treatment, prognosis and complication of Neer Kana Maantham with Acute naso pharyngitis in Modern science.
- To Know the predominance of disease age, sex climate, family history and socio economic status are considered.
- To study the Neer Kana Maantham on basis of siddha parameters such as dearanged Mukkuttram , poripulangal , ezhuudarkattukal and envagai Thervugal.
- To have the clinical trial of Neer Kana Maantham with trial medicine

  OMA KUDINEER in Govt. Siddha .Medical. College & Hospital, Chennai-106

TO EVALUATE:

a. Phyto- chemical screening
b. Physio-chemical screening
c. Anti -microbial
d. Anti -inflammatory
e. Toxicological analysis (Acute)
f. Pharmacological studies
g. Bio-statistical analysis of trial drug

To create awareness among the parents about the prevention of this disease.

REVIEW OF SIDDHA LITERATURE

SIDDHA ASPECT

SIDDHA LITERATURE REVIEW

மாந்தம்

வேறு பெயர்கள்

மாந்தம், அலசம், அலசகம், என பிள்ளை பிணி மருத்துவம் நூலில் குறிப்பிடப்பபட்டுள்ளது .

இயல்

- மந்த இயல்பு உடையது மாந்தம் எனப்படும்.
- மாந்தம் என்பது உருவ நிலையில் உடல் நிலையில் மந்தம்.
- அருவ நிலையில் அகக்கருவிகளாகிய மனம், புத்தி, சித்தம், அகங்காரம் அகிய அனைத்து அந்தக்கரணங்களிலும் மந்தம் என குழந்தை மருத்துவத்தில் கூறப்பட்டுள்ளாது.
- உண்ட உணவு செரியாமல் வயிற்றில் புளித்து வயிறு உப்பி இரைந்து மந்தத்தை உண்டாக்கி வாந்தியையும் கழிச்சலையும் உண்டாக்கி துன்பத்தையும் ஏற்படுத்தும் நோய் என பிள்ளைப்பிணி மருத்துவதில் குறிப்பிடப்பட்டுள்ளது

நோய் வரும் பருவம்:

- இந்நோய் தாலப்பருவம், சப்பாணிப்பருவம், முத்தப்பருவம், வருகைப்பருவங்களில் உண்டாக்ககூடிய நோய்களாகும்.
- குழந்தையின் முதலாண்டிலிருந்து மூன்று ஆண்டுகள் வரைத் தொடரும் என குழந்தை மருத்துவம் மற்றும் தன்வந்திரி குழந்தை வாகடத்தில் உள்ளாது
- இந்நோய் 3 மாதம் முதல் 12 வயது வரை வரக்கூடியது.
- பால் மட்டும் குடிக்கும் பருவம் , பாலும் சோறும் உண்ணும் பருவம், சோறும் மட்டும் உண்ணும் பருவம் ஆகிய முன்று பருவங்களில் மாந்தம் ஏற்படும் என பிள்ளைப்பிணி மருத்துவத்தில் குறிப்பிடப்பட்டுள்ளது.

நோய் வரும் வழி:

- குழந்தை பிறந்த ஒரு ஆண்டிற்குள் நீர் நிலைகளில் பழுத்து உதிர்ந்த சருகுகள் விழுந்து அழுகியிருக்கும் நீரைக்குடிப்பதாலும்.
- எருமைப்பால் ,புளித்த எருமை மோர், எருமை நெய்,வாழைப்பழம், மாம்பழம், தோங்காய், இளநீர், கடலை, வெல்லம், காட்டுத்துவரை, மொச்சைக்கொட்டை, புளியங்கொட்டை, பருப்பு,மாவினாற் செய்யப்பட்ட பொருள்கள்,

அதிரசம், வாயுப்பொருட்கள் ,சோறு இவைகளை அதிகமாக உண்பாடதாலும் மாந்தநோய் உண்டாம் என குழந்தை மருத்துவம் குறிப்பிடுகிறது.

- பாகற்காய்கள்,ஊன்,பெரிய உளுவைமீன்,வாளைமீன்,பன்றி, வரால் மீன், கொண்டைமீன், இவைகளை உண்பாதலும் மாந்த நோய் உண்டாகும் என பிள்ளைப்பிணி மருத்துவதில் குறிப்பிடுகிறது
- உணவினால் மட்டுமின்றி செயலின் வேறுபாட்டாலும் மாந்த நோய் குழந்தையைத் தாக்கும். வறுமை, பசி, துயரம்,மனக்கவலை, பயம், கோபம், இச்சை போன்ற உணர்வுகளால் குழந்தையானது தாக்குறும் போது உணவு செரிக்கும் தன்மையில் மாறுபாடு நிகழ்ந்து மாந்தம் உண்டாகிறது என பிள்ளைப்பிணி மருத்துவம் நூல் கூறுகிறது
- மோதிபால், நெய், கதலிபழம், இளநீர், தோங்காய், புளித்த மோர், மாமிசம், கனிகள், உளுந்து, மொச்சை, புளியம்கொட்டை, உளுவை, கொண்டைமீன், பாகல், சுரை, முதலான வாயுப்பண்டங்களை பால் கொடுக்கும் மாதர்கள் மிகுதியாக நோய் உண்டாகும் என ஆவி அளிக்கும் அமுத முறை சுருக்கத்தில் குறிப்பிடப்பட்டுள்ளது.

நோய் வகைகள்:

குழந்தை மருத்துவத்தில் மாந்தநோய் 21 வகைகளாகப் பிரிக்கப்பட்டுள்ளது

1. வளி மாந்தம்
2. அழல் மாந்தம்
3. ஐயல் மாந்தம்
4. விடம் மாந்தம்

5. போர் மாந்தம்
6. வாலை மாந்தம்
7. சுரம் மாந்தம்
8. நீர் மாந்தம்
9. செரியா மாந்தம்
10. கட்டு மாந்தம்
11. பால் மாந்தம்
12. எரி மாந்தம்
13. துளா மாந்தம்
14. தலை மாந்தம்
15. கணம் மாந்தம்
16. வலிப்பு மாந்தம்
17. சுழி மாந்தம்
18. முக்கு மாந்தம்
19. சந்தி மாந்தம்
20. ஊதல் மாந்தம்
21. வீக்கம் மாந்தம்

இது தவிர மேலும் 10 வகை குறிப்பிடப்பட்டுள்ளது

1.உப்பல் மாந்தம்
2.வாதி மாந்தம்
3.வறட்சி மாந்தம்
4.திட்டு மாந்தம்
5.உளை மாந்தம்
6.அக்கரம் மாந்தம்
7.பேய் மாந்தம்
8.நீர்கணம் மாந்தம்

9.தோட மாந்தம்

10.கருப்பம் மாந்தம் எனவும்,

மற்றொரு வகைப்பாட்டின் படி,எண்வகை மாந்தம் எனக் கீழ்க்கண்ட வகைகள் கொடுக்கப்பட்டுள்ளது

1.பொது மாந்தம்

2.செரியா மாந்தம்

3.தலை மாந்தம்

4.போர் மாந்தம்

5.கட்டு மாந்தம்

6.விட மாந்தம்

7.நீர் மாந்தம்

8.சுழி மாந்தம்

<u>தன்வந்திரி பாலவாகடத்தில்</u> மாந்த நோய் 21 வகைகளாக வகை படுத்தப்பட்டுள்ளது

1.அழல் மாந்தம்

2.ஊதல் மாந்தம்

3.எரி மாந்தம்

4.ஐயம் மாந்தம்

5.கணம் மாந்தம்

6.சந்நி மாந்தம்

7.கரம் மாந்தம்

8.கரி மாந்தம்

9.செரியாமை மாந்தம்

10.தலை மாந்தம்

11.துலை மாந்தம்

12.நீர் மாந்தம்

13.பால் மாந்தம்

14.போர் மாந்தம்

15.முக்கு மாந்தம்

16.வலிப்பு மாந்தம்

17.வளி மாந்தம்

18.வாலை மாந்தம்

19.விட மாந்தம்

20.விக்கம் மாந்தம்

அனுபவ வைத்திய தேவரகசியத்தில் 8 வகைகள்

1.செரியா மாந்தம்

2.பீர் மாந்தம்

3.சுர மாந்தம்

4.விஷ மாந்தம்

5.சுழி மாந்தம்

6.ஊது மாந்தம்

7.நீர் மாந்தம்

8.தலை மாந்தம்

மதலை நூலில் மாந்தம் 13 வகைகளாகப் பிரிக்கப்பட்டுள்ளது.

(கும்ப முனி பாலவாகடம்)

"தோன்றிய வாத பித்தம் சொல்லிய சிலெற்ப மாந்தம்
ஊன்றியதடுக்கு மாந்தம்விச மாந்தம் போர்மாந்தம் தான்
கன்றியபால் மாந்தம் வன்கப மாந்தம் பொது மாந்தம் பின்
வந்திடும் வினையாம் சன்னி வலி சாத்தி பதிமூன்றாதாமே"

அவையாவன:

1.வாத மாந்தம்

2.பித்த மாந்தம்

3.சிலேற்பன மாந்தம்

4.நடுக்கு மாந்தம்

5.விஷ மாந்தம்

6.போர் மாந்தம்

7.பால் மாந்தம்

8.வன்கப மாந்தம்

9.பொது மாந்தம்

10.வினை மாந்தம்

11.சன்னி மாந்தம்

12.வலி மாந்தம்

13.சாத்தி மாந்தம்

பிள்ளைப்பினி மருத்துவம் பாகம் 2 ல் மாந்தத்தின் வகைகள் -53

43 வகை மாந்தங்கள் குறிகுணவிளக்கங்களுடன் காணப்படுகின்றன .

மீதமுள்ள 10 மாந்தங்கள் பெயரளவில் மட்டும் வகைப்படுத்தப்பட்டுள்ளது

குழந்தை மருத்துவத்தில் மாந்தத்தின் பொது குறிகுணங்கள்:

- குழந்தையின் உடம்புசோர்ந்து இருத்தல்
- உடம்பு நோதல்
- மிகுதியான வியர்வை உண்டாதல்
- சுறுசுறுப்பாக இல்லாமல் கண்விழி சிவந்திருத்தல்
- கண்கள்குழி விழுந்து காணல்
- முகம் வெளுத்து ஒரு வகை மங்கிய ஒளி காணல்
- குரல் தளர்ந்து வாய் உலர்ந்து காணல்
- அடிக்கடி வாந்தி ஏற்படல்
- பசி இன்மை காணல்
- சீதமும் மலமுமாகவும், கெட்டுபோனபால் போலவும்,தண்ணீர் போலவும் நிறமாக பேதியாதல்
- கை கால்கள் சூடு இல்லாமல் குளிர்ந்து காணல்
- கையில் தங்காமல் அழதல்

அகிய இக்குறிகள் எல்லாம் மாந்தத்தின் பொது குறிகுணங்கள் என குழந்தை மருத்துவத்தில் குறிப்பிடப்பட்டுள்ளது.

நீர்கண மாந்தம் குறிகுணம் குழந்தை மருத்துவம் {பாலவாகடம் பக்கம்-176}

இருமு மூக்கில் நீர் வடியும்
இடையில் இடையில் சுரங்காயும்
பொருமி வயிறு இரைச்சலுண்டாம்
போதப் பலவித மாய்கழியும்
சொருகுங் கண்ணும் உடம்புமுகம்
சோர்ந்து தலையும் புரட்டலுண்டாம்
மருவி மயக்கம் உண்டாகும்
வருகு நீர்க்கண மாந்தமுமே

குறிகுணங்கள்

- இருமல்
- மூக்கில் நீர் வடிதல்
- சுரம்
- கழிச்சல
- உடல், முகம் சோர்வடைதல்

சித்த மருத்துவ நோய்கணிப்பு:[Diagnosis]

- பிணியறிமுறைமை
- உயிர் தாதுக்கள் [முக்குற்றம்]
- உடல் தாதுக்கள் [ஏழு உடற்கட்டுகள்]
- பருவ காலங்கள்
- ஐவகை நிலங்கள்
- எண்வகைத் தோர்வு
- நீர்க்குறி
- நெய்குறி
- நாடி

மேற்குறிய காரணிகளின் மாறுபாடுகளை ஒன்றுடன் ஒன்று ஒப்பிட்டு நோய் கணிக்கப்படுகிறது.

பிணியறிமுறைமை:

1) பொறியால் அறிதல்
2) புலனால் அறிதல்
3) வினாவுதல்

நீர்கண மாந்தத்தில் நோயாளிக்கு காணும் குறிகுணங்கள்:

I. பொறியால் அறிதல்

மூக்கு- மூக்கு நீர் பாய்தல்

நா - இயல்பு

கண்- சில வேளை கண் சிவத்தல்

காது-இயல்பு

தோல்-இயல்பு

II. புலனால் அறிதல்

ஊறு - இயல்பு

ஒசை- இயல்பு

ஒளி- இயல்பு

சுவை- இனிப்புச்சுவை தெரிதல்

நாற்றம்- மூக்கில் சளி சவ்வு தடிப்புறுதல்

III. வினாவுதல்:

மருத்துவர் நோயாளியிடம் வினாவுதல் மூலம் நோயைக் கணிக்க முடியும் நோயாளியால் பேச முடியாத நேரத்தில் அவன் சுற்றத்தாரிடம் வினாவுதல் மூலம் நோயைக் கணிக்க முடியும்.

உயிர் தாதுக்கள்:

1) வாதம்

நீர்கண மாந்தத்தில் வாதத்தின் நிலை

a) பிராணன் :இயல்பு
b) அபானன்:பாதிப்பு (சிலவளை கழிச்சல் காணல்)
c) வியானன்:பாதிப்பு (உடல் குன்றுதல்)
d) உதானன்:பாதிப்பு (இருமல் காணுதல்)

e) பாதிப்பு (பசியின்மை காணல்)

f) நாகன்: இயல்பு

g) கூர்மன்: இயல்பு

h) கிருகரன்:பாதிப்பு (இருமல், மூக்கில் நீர் வடிதல்)

i) தேவதத்தன்:இயல்பு

j) தனஞ்செயன்

2) <u>பித்தம்</u>

நீர்கண மாந்தத்தில் பித்தத்தின் நிலை:

a) அனற்பித்தம்: பாதிப்பு (பசியின்மை காணல்)

b) இரசக பித்தம்: பாதிப்பு (முகம் வொளுத்துக் காணல்)

c) சாதகபித்தம்: பாதிப்பு (உடல் சோர்வு காணல்)

d) பிராசகம்: இயல்பு

e) ஆலோசகம்: இயல்பு

3) <u>கபம்</u>

நீர்கண மாந்தத்தில் கபத்தின் நிலை:

a) அவலம்பகம்: பாதிப்பு (இருமல்)

b) கிலதேகம்:பாதிப்பு (செரியாமை)

c) போதகம்:இயல்பு

d) தற்பகம்:சிலவேளை கண் சிவத்தல்

e) சந்தீகம்:இயல்பு

<u>உடற்கட்டுகள்:</u>

நீர்கண மாந்தத்தில் உடற்கட்டுகளின் நிலை:

1. சாரம்:பாதிப்பு (உடற்சோர்வு காணல்)
2. செந்நீர்:பாதிப்பு ((முகம் வெளுத்துக்காணல்)
3. ஊன்: இயல்பு
4. கொழுப்பு: இயல்பு
5. என்பு:இயல்பு
6. மூளை:இயல்பு

7. சுக்கிலம்/சுரோனிதம்:-

<u>ஐவகை நிலங்கள்</u>:

நெய்தல் மற்றும் குறிஞ்சி நிலப்பகுதிகளில் நீர்கண மாந்த நோய் தாக்கம் அதிகமாக காணப்படுகிறது.

<u>முக்குற்றங்களும் பருவகாலங்களும்</u>:

கார்காலம் மற்றும்கூதிர்காலம் நீர்கண மாந்த நோய் தாக்கம் அதிகமாக காணப்படுகிறது. கபக்குற்றம் அதிகரித்து தனக்கு துணையாக வாத ,பித்தக்குற்றத்தை அதிகரித்து இந்நோய் உண்டாகிறது

<u>எண்வகை தேர்வு</u>:

"நாடிப் பரிசம் நாநிறம் மொழிவிழி
மலம் மூத்திரமிவை மருத்துவராயுதம்"

நீர்கண மாந்த்தில் 8 வகைத் தேர்வு

1. நா-இயல்பு
2. நிறம்-முகம் வெ ளுத்துக்காணல்
3. மொழி-குரல் ஒலி தாழ்தல்
4. விழி -சிலவேளை கண் சிவத்தல்
5. மலம்- சிலவேளை கழிச்சல் காணல்
6. மூத்திரம்-இயல்பு
7. பரிசம்-மித வெப்பம்
8. நாடி -வாதபித்தம்,வாதகபம்,பித்தகபம்

<u>நீர்க்குறி</u>:

"அருந்துமாறி ரதமும் அவிரோதமாய்
அ஼கல் அலர்தல் அகாலவூன் தவித்தழற்
குற்றளவருந்தி உறங்கி வைகறை
ஆடிக் கலசத் தாவியே காதுபெய்
தொரு முசகூர்த்தக் கலக்குட்படு நீரின்
நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே"

நோய் நாடல் நோய் முதல் நாடல் பகுதி-1

விளக்கம்:

நீர்க்குறி பார்க்கும் முதல் நாள் இரவு உணவுஉண்டு உறங்க வேண்டும்.பின் விடியற்காலை படிகபாத்திரத்தில் நீரினைப்பிடித்து அதன் நீர்க்குறி மற்றும் நிறக்குறியினை கண்டறிதல் வேண்டும்.

'வந்த நீர் கரியெடை மணம் நுரைஏஞ்சலென்
றைந்தியலுளவை யரைகுது முறையே'

நீரில்

1-நிறம்

2-மணம்

3-நுரை

4-எடை

5-எஞ்சல் .இவற்றை காண வேண்டும்.

நெய்க்குறி:

"நிறக்குறிக் குரைத்த நிருமாண நீரிற்
சிறக்க வெண்ணெய்யோர் சிறுதுளி நடுவிடுத்
தென்றுறத் திறந்தொலி யோகா தமைந்ததி
னின்ற திவலை போம் நெறிவிழியறியும்
சிறுநீரில் நல்லெண்ணெய் விட்டு பார்ப்பது"

நோயாளியின் சிறுநீரை சோதனை வட்டிலில் ஊற்றி சூரிய ஒளி மிகுந்த இடத்தில் நீரின் அலையில்லாத போது நல்லெண்ணெய்த்துளி விட்டு பார்ப்பது

"அரவென நீண்டினஃதே வாதம்
ஆழி போற் பரவின் பித்தம்
முத்தொத்து நிற்கின் கபம்"

வாத நீர் -பாம்பு போல் பரவும்

பித்த நீர்-மோதிரம் போல் பரவும்

கப நீர்-முத்து போல் பரவும்

நீர்கண மாந்தத்தில் நாடி நடை:

வாதபித்தம்

வாதகபம்

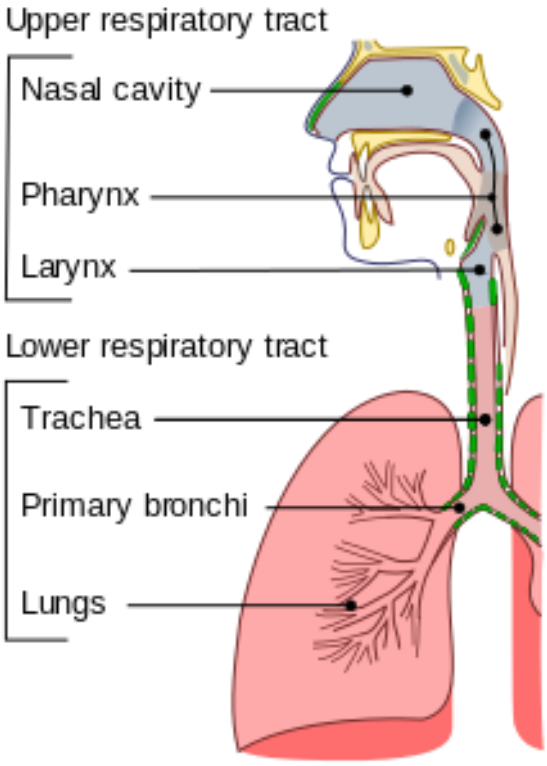
பித்தகபம்

MODERN ASPECT

MODERN ASPECT

RESPIRATORY SYSTEM

Respiratory system is one of the important system in our body , plays main role in respiration. Its divided into upper and lower airways. The upper respiratory tract includes nose, para nasal sinusitis, pharynx, larynx. Lower respiratory tract includes trachea, bronchi, bronchioles and alveoli.



UPPER RESPIRATORY TRACT

Upper Respiratory Tract refers to the parts of respiratory system lying above the sternal angle, above the glottis. It includes the nose, the naso pharynx and the oropharynx. It plays main role in fighting with the infection which affects the human being through oral and mucosal route.

ANATOMY & PHYSIOLOGY OF UPPER RESPIRATORY TRACT

NOSE

- The nose is the visible part of the respiratory system.
- Protruding prominently from the face, the nose serves as a vent for air exchange and also as the organ of smell.
- The structures of the nose are divided into two main parts, the **External nose** and the **internal nasal cavity**.
- The **external nose** has a skeletal frame work that is a) partly **bony** and b) partly **cartilaginous**.
- The bones are the nasal bones which form the bridge of the nose and the frontal process of the maxillae.
- The cartilages are the superior and inferior nasal cartilages, the septal cartilage and Some small cartilages.
- The nasal cavity extends from the external nares to the posterior nasal apertures.
  It is sub divided into right and left halves by a midline nasal septum.
  Each half has a:
    - Floor-separates it from oral cavity, formed by the hard palate
    - Roof-narrow & formed by the
        1. Body of sphenoid
        2. Cribriform plate of ethmoid bone
        3. Frontal bone
        4. Nasal bone &cartilage
    - Lateral wall

      Shows three horizontal bony projections, covered by mucous membrane, the superior, middle & inferior conchae.
    - Medial wall (septum)

      Osteocartilagenous partition, covered by the mucoperiosteum

      Formed by-superiorly- the vertical plate of ethmoid bone

      Posteriorly-the vomer bone

      Anteriorly-the septal cartilage

Arterial supply

1. Ant ethmoidal artery

2. Post ethmoidal artery
3. Sphenopalatine artery
4. Greater palatine artery
5. Superior labial artery

Venous supply

1. Trigeminal nerve
2. Ant superior-ophthalmic nerve
3. Ant inferior-maxillary nerve
4. Post superior-maxillary nerve

PHARYNX:

- The pharynx is a wide muscular tube, situated behind the nose, the mouth and the larynx.
- Length: About 12 cm
- Width: Upper part is widest and collapsible(3.5cm)

  Middle part is narrow

  Lower end is the narrowest of the gastro intestinal tract
- Clinically it is a part of the upper respiratory tract where the infections are common.
- It is divided into 3 parts.

  1. Nasopharynx

  It is the upper part situated behind the nose and above the lower border of soft palate and it transmit only air.

  2. Oropharynx

  It is the middle part of the pharynx situated behind the oral cavity and it transmits both air and food.

  3. Laryngopharynx

  It is the lower part.it extends from the upper border of epiglottis to the lower border of cricoid cartilage and it transmit only food
- Boundaries

  Superiorly

  Base of the skull

  Posterior part of the body of the sphenoid

  Basilar part of the occipital bone

  In front of the pharyngeal tubercle

  Inferiorly

Continuous with oesophagus

Lower border of cricoid cartilage

Posteriorly

Prevertebral fossa

Anteriorly

It communicates with the nasal cavity, oral cavity, and larynx. The anterior wall of the Pharynx is incomplete.

Laterally

It communicates with middle ear cavity

Mandible

Tongue

Pterigoid plate

Hyoid bone

Thyroid

- **Muscle of the pharynx**

The muscular basis of the wall of the pharynx is formed by 3 pairs of constrictors namely Superior, middle and inferior constrictors.

- **Nerve supply**

Pharyngeal branch of the vagus

Pharyngeal branches of the glosso pharyngeal nerve

Pharyngeal branches of superior cervical sympathetic ganglion

Cranial accessory nerve

Maxillary nerve

- **Blood supply**

Arteries

Ascending pharyngeal branch of the external carotid artery.

Ascending palatine and tonsilar branches of the facial artery.

Dorsal lingual branches of the lingual artery.

The greater palatine pharyngeal and pterigoid branches of maxillary artery.

Veins

Internal jugular vein

Facial vein

Lymphatics

Retropharyngeal, deep cervical lymph nodes.

Physiology

The functions of nose are

1. Provides an Airway for Respiration
2. Moistens and Warms Entering Air
3. Filters Inspired Air and Cleanses It of Foreign Matter
4. Serves as a Resonating Chamber for Speech
5. Houses the olfactory (smell) receptors

The functions of pharynx are

1. Respiration
2. Swallowing
3. Language formation
4. Protective function

ACUTE NASO PHARYNGITIS

(COMMON COLD)

Acute naso pharyngitis is commonly known as cold. It is an inflammation of the mucous membranes of the upper pharynx, the naso pharynx or the naso pharyngeal duct which extends between the oral and nasal palate. It is also referred as upper respiratory infection or rhinitis. It is very common pathology among children and adolescents.

ETIOLOGY

It has both Infective and non-infective cause. Non infective cause like allergic to food, Low socio economic status , Dust allergy ,environmental changes like pollution ,climate change and family history can causes naso pharyngitis. A virus or bacteria causes infective naso pharyngitis. Although viruses causes most acute naso pharyngitis episodes, group A streptococcus causes 37% of infection in children older than 5 years ,other bacterial cause of infection are group C streptococcus (5%),anaerobic species (1%) .Between viruses Rhino virus, Corna virus and Adeno virus account for the 30% of total case. It can spread through tiny air droplets that are expelled when a person infected sneezes.

EPIDEMOLOGY

Naso pharyngitis exists latently in a large number of people and pathological examination revealed the presence of inflammation in all subjects aged from 12hours after birth to 80 years. Streptococcal pharyngitis has a peak incidence in early school years. Illness occurs most often in winter & spring. The infection is transmitted via respiratory secretions and the incubation period is 2-5 days. Communicability of infection is highest during acute phase and in untreated people gradually diminishes over a period of weeks.

PATHOLOGY

The symptoms of the common cold are believed to be primarily related to the immune response to the virus. The mechanism of this immune response is virus specific. For example, the rhinovirus is typically acquired by direct contact; it binds to human ICAM-1 receptors through unknown mechanisms to trigger the release of inflammatory mediators. These inflammatory mediators then produce the symptoms. It does not generally cause damage to the nasal epithelium.

The respiratory syncytial virus (RSV), on the other hand, is contracted by direct contact and airborne droplets. It then replicates in the nose and throat before frequently spreading to the lower respiratory tract. Respiratory syncytial virus does cause epithelium damage. Human Para influenza virus typically results in inflammation of the nose, throat, and bronchi. In young children when it affects the trachea it may produce the symptoms of croup due to the small size of their airways.

CLINICAL MANIFESTATIONS:

IN YOUNGER CHILDREN

- In General, children 3 months-3 years have fever in the early course of infection.
- Few hours before onset of fever, sneezing, irritability and restlessness present.
- Nasal discharge begins within few hours quickly leading to nasal obstruction.
- A few infant may vomit and some have diarrhea

IN OLDER CHILDREN

- The initial symptoms are dryness and irritation in the nose , these symptoms follow with in few hours
- Watery nasal discharge
- Sneezing
- Coughing
- Muscular aches
- Head aches
- Malaise
- Anorexia
- Low grade fever may be present

Common Cold Complications

- Sinus infection (acute sinusitis) Acute sinusitis is characterised by inflammation and swelling of the mucous membranes that line your sinus cavities
- Asthma attack
- Acute bronchitis (chest cold)
- Sore throat and tonsillitis.
- Acute suppurative otitis media
- Pneumonia

TRIAL DRUG

Trial Drug

Trial drug

PREPARATION AND PROPERTIES OF TRIAL DRUG

OMA KUDINEER

Ref: Balavagadam, page 67

Ingredients:

1. Pepper-35gm {1palam}
2. Long pepper-35gm{1 palam}
3. Garlic-35gm{1palam}
4. Omam-35gm {1palam}

Method of preparation:

All the drugs were taken equal ratio purified and grinded to the powder form. Required quantity is taken from the grinded powder and mixed with1300mlof pure water and this mixture is boiled until the concentrated170ml decotation of the ingredient is obtained

Dose: 4-8ml depending upon age (twice a day)

Duration: 7 days

திப்பிலி

Botanical Name: *Piper longum*

English Name: Long pepper

Family:piperacea

Suvai: kaarppu

Thanmai: veppam

Pirivu: Inippu

Used part:seed

பொது குணம் :

“ ஈளை யிருமல் லிரைப்பு பசப்பிணிகள்

மாள வொழியாமல் வாட்டுமே -யாளுமுறை

பாங்கா யறிந்து செய்வீர் பண்டிதத்தைப் பண்டிதரே

வேங்கைவாய் பான்கனை மெய்."

- தேரன் வெண்பா

Chemical constituents: piperine ,piperlongumine

Actions: stimulant, carminative

Pharmacological activity: anti-bacterial

மிளகு

Botanical Name: *Piper nigrum*

English Name:pepper

Family:piperacea

Suvai:kaarppu,kaippu

Thanmai:Veppam

Pirivu:kaarppu

Used part:Seed

பொது குணம் :

தீயாகி யெங்கும் திரியுமதை யாவத்து
மோயாம லெப்படியு முண்டாக்காற் -பாயாது
போந்திமிர்வா தங்கிரந்தி புண்ணீரும் மண்ணவக்கும்
காந்திமெய்வா தச்சலுப்பைக் காய்.

\- தேரன் வெண்பா

Chemical constituents:piperine,piperidine,chavicine

Actions:stimulant, antiperiodic,carminative,antidote

Pharmacologicalactivities:Anti-bacterial,analgesic,Anti-histamine,anti-inflammatory

ஓமம்

BotanicalName: *Carum copticum*

English Name:Oman

Family:Apiaceae

Suvai: kaarppu

Thanmai:Veppam

Pirivu: kaarppu

Used part:seed

பொது குணம்:

சீதசுரங் காசஞ் சொயாமந்தம் பொருமல்
பேதியிரைச் சல்கடுப்பு பேராம் -ஓதிருமேல்
பல்லொடுபல் மூலம் பகமிவைநோ யென்செயுமோ
சொல்லொடுபோம் ஓமமெனச் சொல்.

- அகத்தியர் குணவாகடம்

Chemical constituents:Thymol,gamma-terpinene,p-cymenea

Actions:carminative,tonic,stomachic

Pharmacological activities:tonic,antiseptic,carminative

வெள்ளுள்ளி

Botanical Name : *Allium sativum*

English Name:garlic

Family:Amaryllidaceae

Suvai: kaarppu

Thanmai: Veppam

Pirivu: kaarppu

Used part:tuber

பொதுகுணம்

சன்னியொடு வாதந் தலைநோவு தாள்வலி
மன்னிவரு நீர்க்கோவை வன்சீதம்-அன்னம்!
உள்ளுள்ளி கண்பாய் உளைமூல ரோகமும் போம்
வெள்ளுள்ளிதன்னால்வெருண்டு.

. -அகத்தியர் குணவாகடம்.

Chemical constituents:Alliin,ajoene

Actions: Expectorant, stomachic, tonic, carminative

Pharmacological activities:expectorant,stimulant,carminative

MATERIALS AND METHODS

MATERIALS AND METHODS

CLINICAL STUDIES:

After finishing the toxicity studies 40 paediatric cases were selected on the basis of inclusion criteria from the OPD of Kuzhanthai Maruthuvam Department, Arignar Anna Govt Hospital, Chennai. They were treated with the trial drug Oma kudineer and observed for prognosis clinically

Study Design

A clinical trial on Neer kana Mantham was carried out in the post graduate department of kuzhanthai maruthuvam in Govt.Siddha.Medical.College attached to Aringar Anna Hospital of Indian Medicine, Chennai-106 during the period of 2015-2017

The study was approved by Institutional Ethics Committee [IEC] and the approval number is IEC **No: GSMC-CH-ME-4/020/2015**

Sample size

The study is conducted in 40 selected patients of both genders between age groups of 2 to 12 years

Inclusion Criteria:

- Age 2-12 yrs.
- Running Nose.
- Cough.
- Fever
- Malaise.
- Diarrhoea.

Patient having any three symptoms are included in my trial

Exclusion Criteria

- Bronchitis.
- Bronchial Asthma.
- Severe Diarrhoea.

Withdrawal Criteria

- Exacerbation of the symptoms.
- Occurrence of any adverse effects.
- Patients turned to unwilling during follow up.

Assessments and Investigations

Clinical Assessment

- Rhinorrhoea.
- Cough.
- Fever.
- Malaise
- Loss of appetite

Siddha Assessment

- Naa
- Niram
- Mozhi
- Vizhi
- Sparism
- Malam
- Naadi
- Moothiram-Neer Kuri ,Nei Kuri

Routine Tests and Investigations

Blood: TC, DC, ESR, Hb.

Urine: Albumin, Sugar, Deposits.

Methodology of Treatment

Study Enrolment:

Patient reporting at the OPD associated with clinical features of Running nose, cough, fever, malaise, fatigue are chosen for enrolment based on the inclusion criteria. The patients who are enrolled are informed about the study trial drug, possible outcomes and the objectives of the study in the language ant terms understandable to them and then informed consent/assent would be obtained from the patient/patients parent using consent/Assent form.

Conduct of the Study:

The trial drug will be given in the OPD department of Kuzhanthai Maruthuvam, GSMC, and Chennai. The patients will be asked to have a regular follow up in the OPD department once in 3days. In each and every visit the clinical assessment will be recorded in the prescribed proforma. The laboratory investigation will be done before and after treatment and recorded in the prescribed format.

Data collection forms:

Required information will be collected from each patient by using following forms.

Form I : Screening and selection proforma.

Form II : History taking proforma.

Form III : Clinical assessment proforma.

Form IV : Clinical assessment during and after trial.

Form V : Laboratory Investigation proforma.

Form VI : Informed consent/Assent form.

Form VII: Withdrawal form.

Form VIII: Patient information sheet.

Data Analysis:

After enrolling the patients in the study a separate file for each patient will be maintained and all forms will be kept in the file. Whenever the patient visits OPD during the study period necessary entries will be made in the assessment forms. The data entries and adverse events if any will be monitored by the Head of the Department.

Outcome of Treatment:

Primary Outcome:

Primary outcome is mainly assessed by comparing the reduction in clinical symptoms and recurrence before and after treatment.

Secondary Outcome:

Secondary outcome is assessed by comparing the safety parameters before and after treatment.

Adverse effect and Serious effect Management:

If the trial patient develops any adverse reactions the patient will be referred to the Pharmacovigilance department of SCRI and documented. For any adverse effect the investigator will give the proper management in the OPD.

Ethical issues:

1. Informed consent/Assent will be obtained from the patient/patient's parent or guardian after explaining about the clinical trial in an understandable language
2. After the consent/Assent of the patient or patient's parent (through consent/Assent) if they fit in the criteria they will be enrolled in the study.
3. Treatment will be provided free of cost.
4. Concomitant medicines will be used if there is any need.
5. The patients who are excluded (as per the exclusion criteria) will be refer to OPD
6. In conditions of treatment failure, adverse reaction patients will be given rescue medication.

RESULTS AND OBSERVATIONS

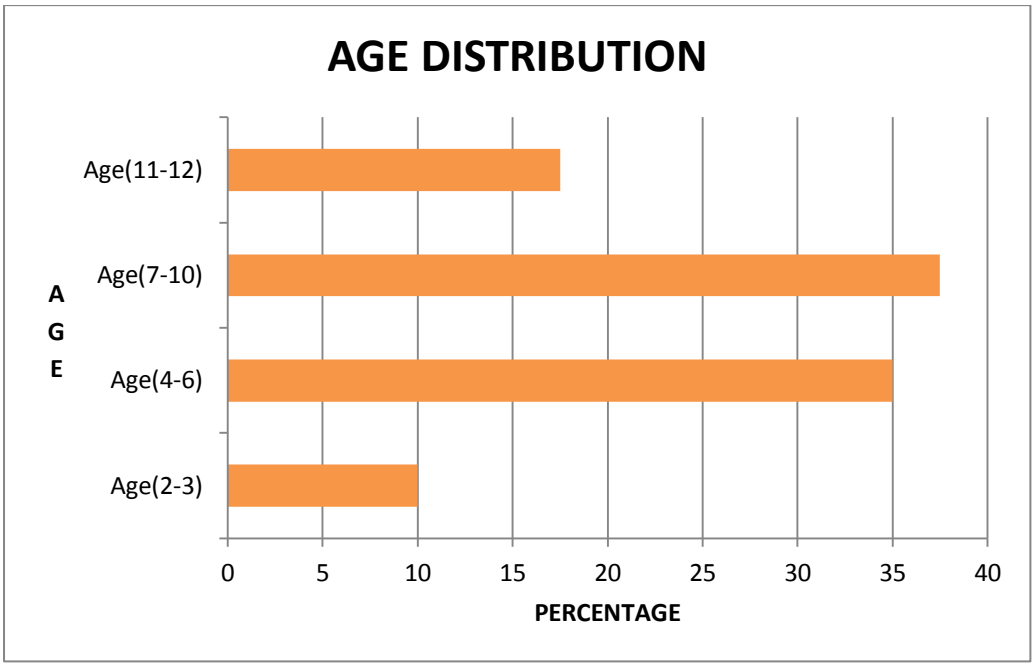
RESULTS AND OBSERVATIONS

A total number of 40 child patients with signs and symptoms of Neer Kana Mantham attending PG-IV, Kuzhanthai Maruthuvam Out Patient Department in Govt. Siddha Medical College attached to Aringnar Anna Hospital were observed in the present study. The observations were made and tabulated with regards to the following features:

1. Age Distribution
2. Gender Distribution
3. Family History
4. Diet history
5. Socio-Economic status
6. Uyirthathukkal
7. Udarthathukkal
8. Envagai thervugal
9. Neikkuri
10. Thinai
11. Paruvakaalam
12. Clinical Features
13. Prognosis
14. Result

1. AGE DISTRIBUTION

SNO	Age	No of Cases(out of 40)	Percentage
1	2-3 years	4	10%
2	4-6 Years	14	35%
3	7-10 Years	15	37.5%
4	11-12 Years	7	17.5%

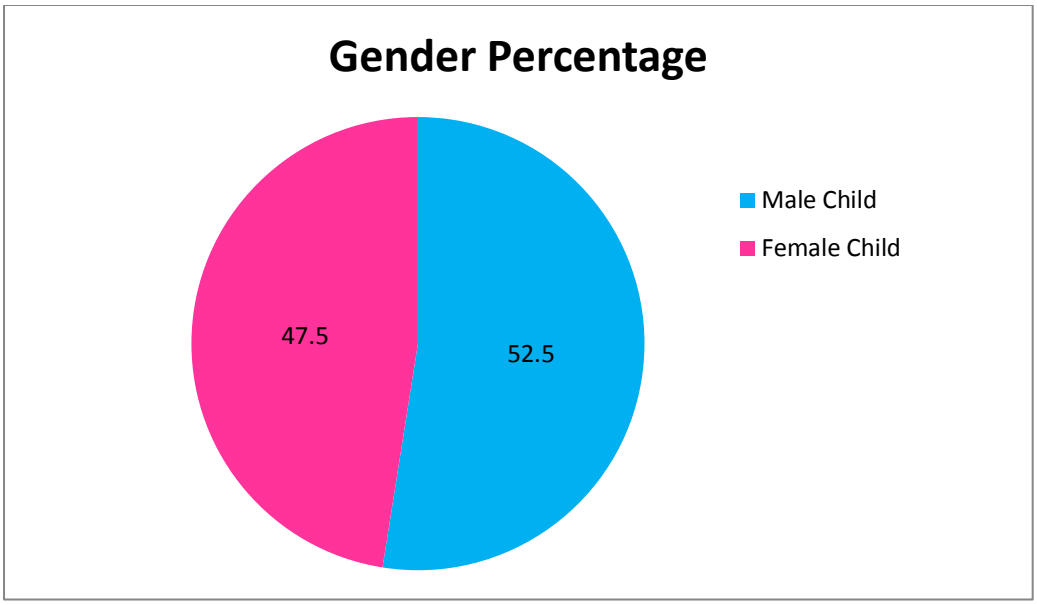


Inference:

The above table indicates that children coming under 2-3 yrs. of age group were 10%, 4-6yrs were 35%, 7-10 yrs were 37.5% and 11-12 yrs were 17.5% respectively.

2. GENDER DISTRIBUTION

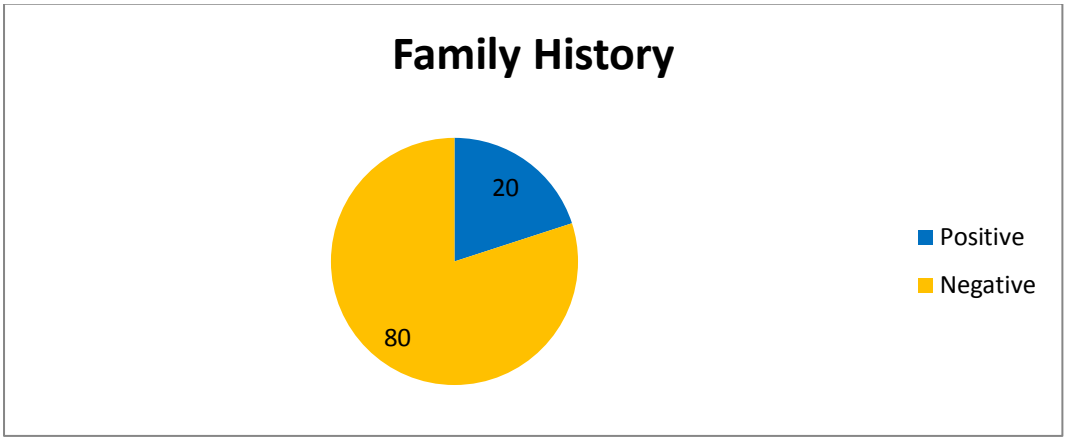
Gender	No of Patients	Percentage
Male Child	21	52.5%
Female Child	19	47.5%
Total	40	100



Inference:
Among 40 cases for this study, 21 children ie 52.5% were male and 19 children ie 47.5% were female.

3. FAMILY HISTORY

SNO	Family History	No of Cases(out of 40)	Percentage
1	Positive	8	20 %
2	Negative	32	80 %

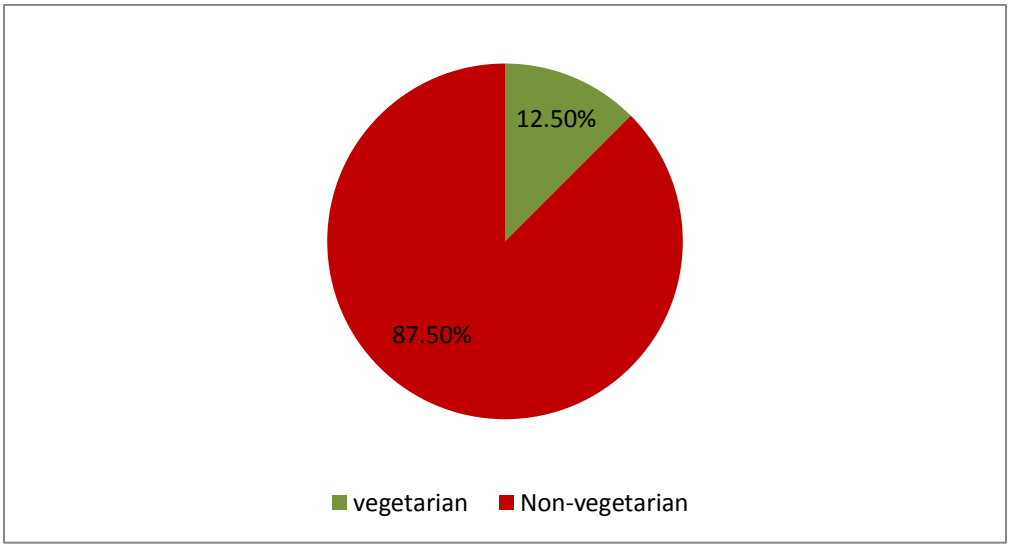


Inference:

Out of 40 cases, family history is positive in 8 cases ie 20% and negative in 32 cases ie 80%.

4. DIET HISTORY

Dietary habits	No of cases out of 40	Percentage
vegetarian	5	12.5%
Non -vegetarian	35	87.5%

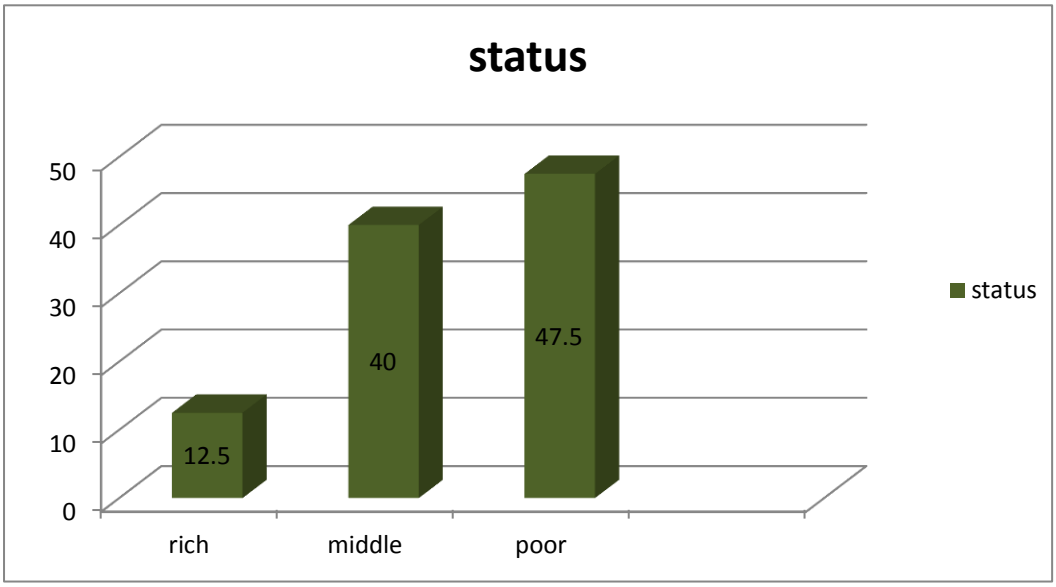


Inference:

Out of 40 cases, 5 cases were vegetarian ie 12.5% and 35 cases were non-vegetarian ie 87.5%.

5. SOCIO ECONOMC STATUS

S.No	Status	No. of cases	Percentage
1	Rich	5	12.5%
2	Middle	16	40%
3	Poor	19	47.5%



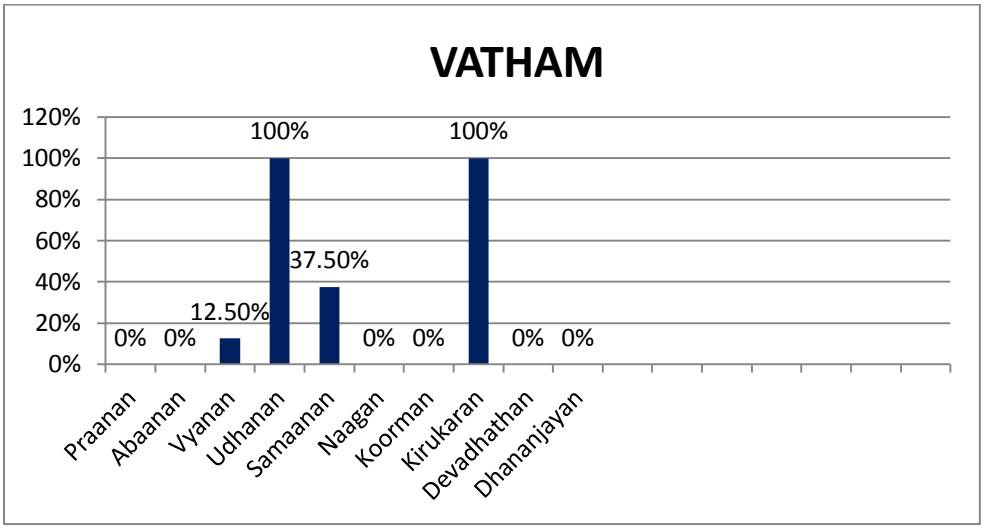
Inference:

Out of 40 cases, 5 were rich ie 12.5%, 16 were middle ie 40% and 19 were poor ie 47.5%.

6. UYIRTHATHUKKAL

I. Vatham

S.No.	Vatham	No. of cases out of 40	Percentage
1.	Praanan	-	-
2	Abaanan	-	-
3	Vyanan	5	12.5%
4	Udhanan	40	100%
5	Samaanan	15	37.5%
6	Naagan	-	-
7	Koorman	-	-
8	Kirukaran	40	100%
9	Devadhathan	-	-
10	Dhananjayan	-	-

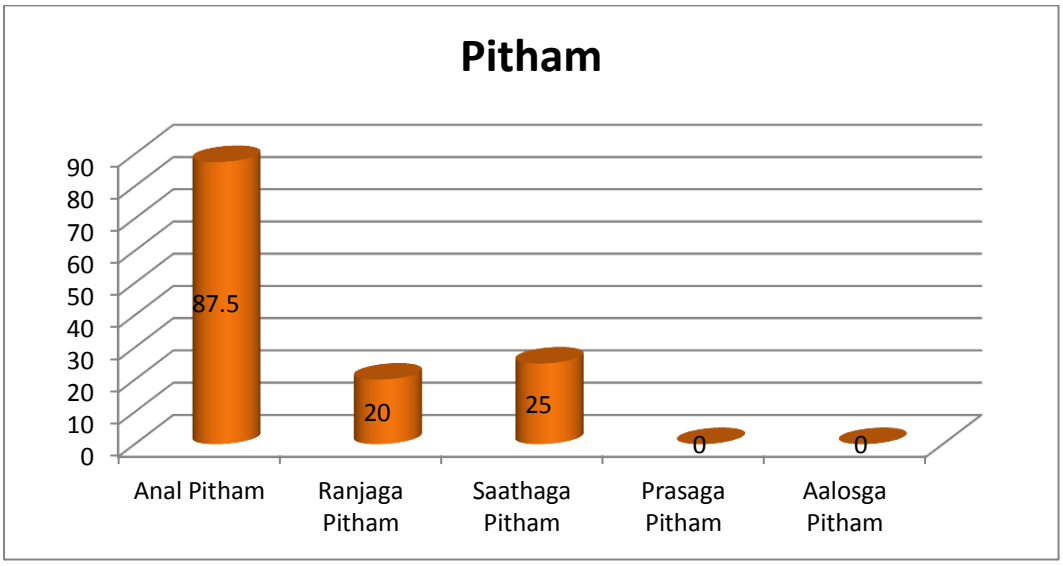


Inference:

In vatham, vyanan was affected in 5 cases ie 12.5%, samaanan was affected in 15 cases ie 37.5%, udhanan and kirukaran was affected in all 40 cases ie 100%

ii)Pitham:

S.NO	Pitham	No of cases	Percentage
1	Anal Pitham	35	87.5%
2	Ranjaga Pitham	8	20%
3	Saathaga Pitham.	10	25%
4	Prasaga Pitham	-	-
5	Aalosaga Pitham	-	-

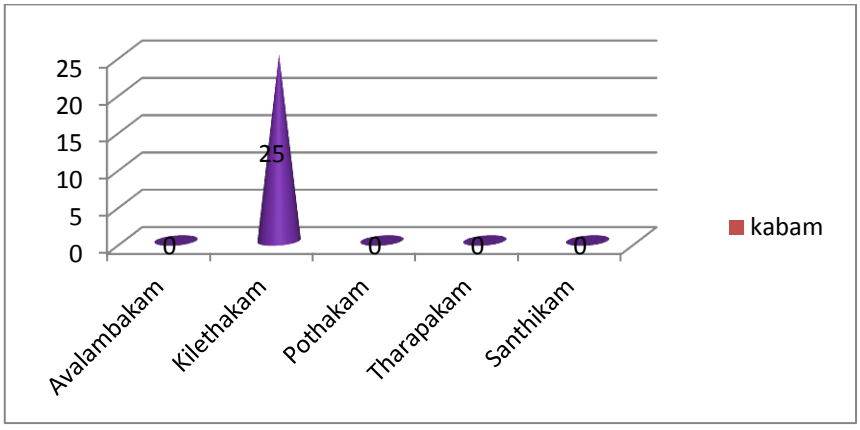


Inference :

In Pitham, Anal pitham was affected in 35 cases ie 87.5%, Ranjaka pitham was affected in 8 cases ie 20%, and saathaga pitham was affected in 10 cases ie 25%.

Iii) *Kabam*:

s.no	Kabam Types	No of cases out of 4(	Percentage
1	Avalambakam	-	-
2	Kilethakam	10	25%
3	Pothakam	-	-
4	Tharapakam	-	-
5	Santhikam	-	-

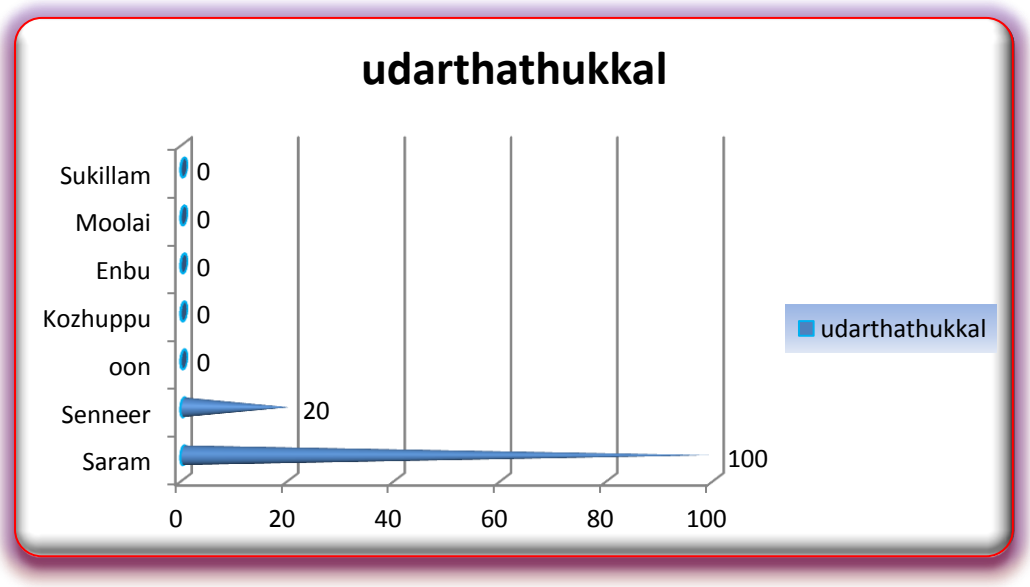


Inference:

In kabam, kilethakam was affected in 10 cases ie 25%.

7. Udarthathukkal:

S.No	Udarthathukkal	No Of Cases Out Of 40	Percentage
1	Saaram	40	100%
2	Senneer	8	20%
3	Oon	-	-
4	Kozhuppu	-	-
5	Enbu	-	-
6	Moolai	-	-
7	Sukillam/Suronitham	-	-

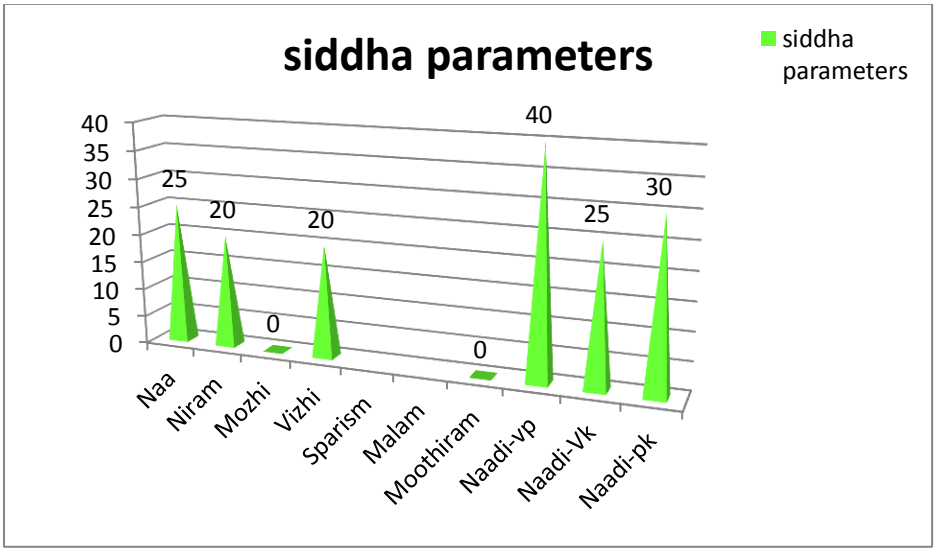


Inference:

In udharthathukkal, saaram was affected in 40 cases ie 100% and senner was affected in 8 cases ie 20%.

8. Envagai thervugal:

s.no	Siddha parameter	No Of Cases Affected	Percentage
1	Naa	10	25%
2	Niram	8	20%
3	Mozhi	-	-
4	Vizhi	8	20%
5	Sparism	11	27.5%
6	Malam	-	-
7	Moothiram	-	-
8	Naadi A.Vathapitham B.Vatha Kabam C.Pitha Kabam	 16 10 14	 40% 25% 35%

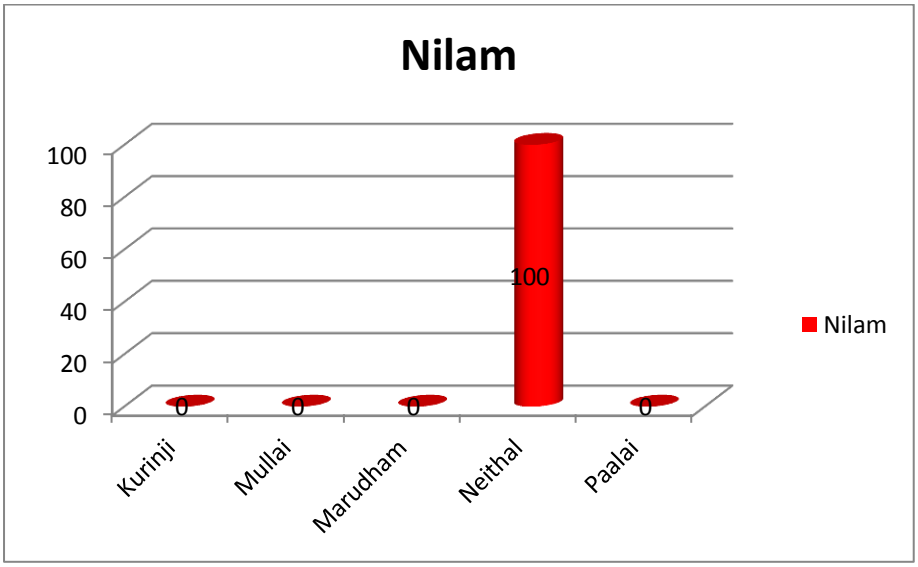


Inference:

In envagai thervugal, Naa was affected in 25% cases, Niram and vizhi was affected in 20% cases and sparisam was affected in 27.5% cases. In case of Naadi was seen as vatha pitham in 16 cases ie 40%, vathakabam in 10 cases ie 25% and pitha kabam in 14 cases ie 35%.

9.Nilam:.

S.No	Nilam	No Of Cases Out Of 40	Percentage
1	Kurinji	0	-
2	Mullai	0	-
3	Marudham	0	-
4	Neithal	40	100%
5	Paalai	0	-

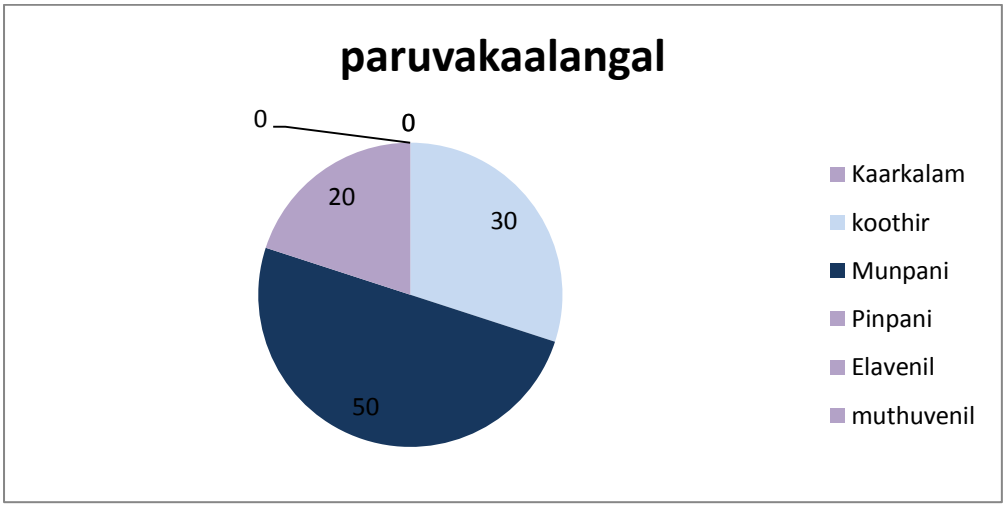


Inference

All the 40 cases were reported from surroundings of Chennai which is belongs to Neithal Nilam and kaba diseases is more prevalent in Neithal Nilam

10. Paruvakaalam:

S.No	Paruvakaalam	No Of Cases Out Of 40	Percentage
1	Kaarkaalam	0	0
2	Koothirkaalam	12	30%
3	Munpanikaalam	20	50%
4	Pinpanikaalam	8	20%
5	Elavenilkaalam	0	0
6	Muduvenilkaalam	0	0

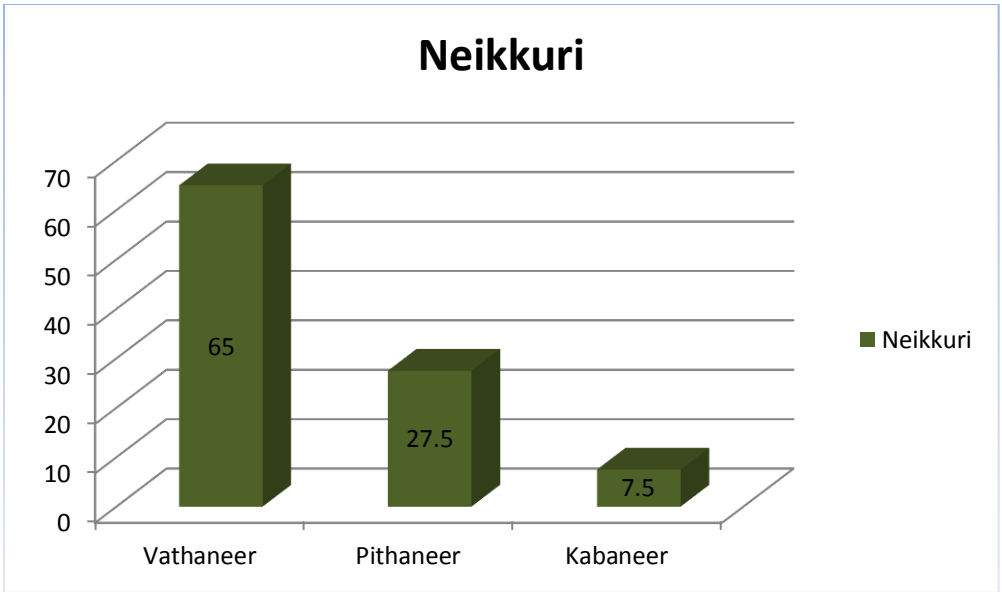


Inference:

The table shows that more prevalence of the disease is under Munpanikalam-50% ,30% of children were affected in Koothirkalam and 20% were affected in pinpanikalam.

11. Neikkuri

S.No	Neikkuri	No Of Cases Out Of 40	Percentage
1	Vathaneer	26	65%
2	Pithaneer	11	27.5%
3	Kabaneer	3	7.5%

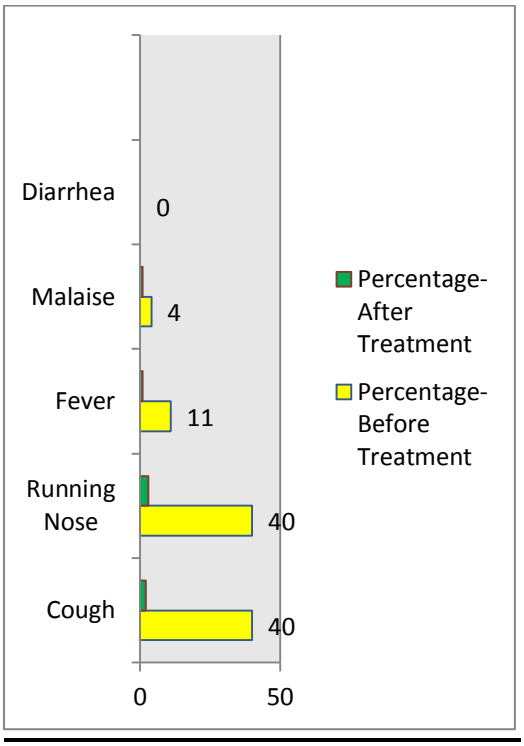


Inference:

Among 40 cases, vathaneer was observed in 26 cases ie 65%, pithaneer was observed in 11 cases ie 27.5% and kabaneer was observed in 3 cases ie 7.5%.

12. CLINICAL PROGNOSIS

SNO	CLINICAL FEATURES	BEFORE TREATMENT		AFTER TREATMENT	
		NO of cases (out of 40)	Percentage	NO of cases (out of 40)	Percentage
1	Cough	40	100	2	5
2	Running Nose	40	100	3	7.5
3	Fever	11	27.5	1	2.5
4	Malaise	4	10	1	2.5
5	Diarrhea	0	0	0	0

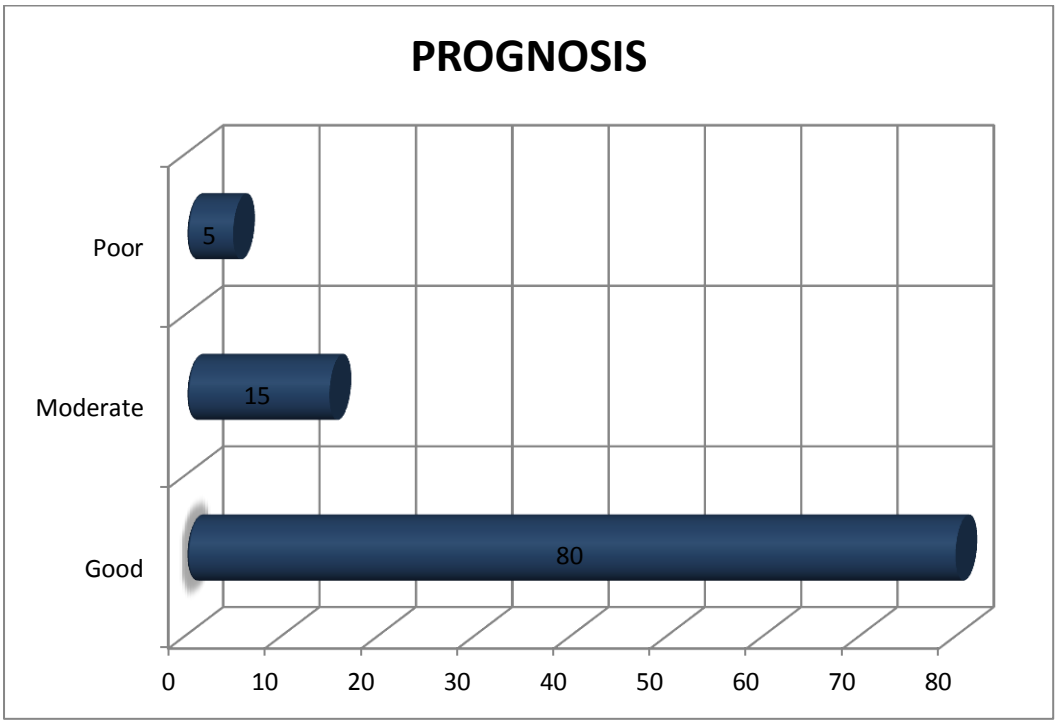


Inference:

The above table reveals that, among 40 cases, had cough 100% before treatment was reduced to 5% and 100% of cases had Running nose before treatment was reduced to 7.5% .27.5% cases had Fever was reduced to 2.5% after treatment.

13. RESULTS OF NEER KANA MAANTHAM

SNO	Prognosis	No of Cases (Out of 40)	Percentage (%)
1	Good	32	80
2	Moderate	6	15
3	Poor	2	5



Inference:

Among 40 patients, 32((80%) cases showed good improvement, 6(15 %) cases showed moderate improvement, 2(5%) cases showed mild improvement.

CASE SUMMARY OF THE PATIENTS

SNO	OP.NO	Name	Age/Sex	Days treated	Remarks
1	4438	Shifa	2yrs/Fc	9	Good
2	6157	Kaviyasree	21/2 yrs/Fc	7	Good
3	4596	Nasser	3yrs/Mc	8	Good
4	9883	Yuvan Shankar	31/2 /Mc	11	Good
5	6644	Veeras	4yrs/Mc	6	Moderate
6	9921	Prajan	4 yrs/Mc	7	Moderate
7	9720	Sanjana	4yrs/Fc	11	Good
8	7745	Sagithya	4yrs/Fc	9	Good
9	7414	Devmadhavan	5yrs/Mc	10	Good
10	238	Ashwin karthick	5yrs/Mc	8	Good
11	562	Ganesh kumar	5yrs/Mc	10	Moderate
12	5981	Kaanishka	5yrs/Fc	9	Good
13	7617	Priyadarshini	6yrs/Fc	7	Good
14	5114	Harifa	6yrs/Fc	7	Good
15	8102	Aswin	6yrs/Mc	8	Good
16	5694	Srinivedha	6yrs/Fc	7	Good
17	7540	Sharon	6yrs/Mc	6	Good
18	1752	Akash	6yrs/Mc	9	Good
19	2172	Nitish	7yrs/Mc	8	Good
20	5795	Sridhar	7yrs/Mc	7	Moderate
21	3754	Keerthana	7yrs/Fc	6	Good
22	3847	Shakilabanu	7yrs/Fc	7	Good
23	3869	Banbalan	8yrs/Mc	5	Moderate
24	6650	Nirekha	81/2yrs/Fc	6	Good
25	1320	Bhavadarini	9yrs/Fc	8	Good
26	2702	Rithika	9yrs/Fc	7	Good
27	4524	Swetha	9yrs/Fc	10	Moderate
28	5636	Karthick	91/2 yrs/Mc	8	Good
29	9564	Udhya saravanan	9yrs/Mc	10	Good
31	3958	Gunapriya	10yrs/Fc	5	Good
32	6358	Surendar	10yrs/Mc	7	Good
33	3256	Sanjana	10yrs/Fc	7	Good
34	5709	Abi	11yrs/Fc	8	Good
35	9963	Rithika	11yrs/Fc	10	Mild
36	398	Akshaya	11yrs/Fc	8	Good
37	6769	Charles	12yrs/Mc	7	Good
38	2261	Kalaiselvan	12yrs/Mc	8	Good
39	5690	Sarvendiran	12yrs/Mc	7	Good
40	5640	Sansi	12yrs/Mc	7	Good

S NO	OPNO	NAME	AGE\SEX	Haematological Analysis														URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT				ESR(MM)				HB(gms%)							
				TC(Cu)	DC			TC	DC			BT		AT		BT	AT	BT			AT		
					P%	L%	E%		P%	L%	E%	1/2hr	1hr	½ hr	1hr			Alb	Sug	Dep	Alb	Sug	Do
1	4438	Shifa	2ys/Fc	12900	39	50	11	12000	55	39	6	22	53	15	39	11.6	12	Nil	Nil	Nil	Nil	Nil	N
2	6157	Kaviyasree	21\2ys/Fc	14100	71	23	6	13900	65	30	6	5	12	4	10	10.6	11	Nil	Nil	Nil	Nil	Nil	N
3	4596	Nasser	3ys/Mc	13100	56	35	9	12600	54	40	6	4	12	3	11	9.2	10.5	Nil	Nil	Nil	Nil	Nil	N
4	9883	Yuvan Shankar	31\2ys/Mc	10900	63	31	6	10100	59	46	5	5	15	4	12	13.2	13.6	Nil	Nil	Nil	Nil	Nil	N
5	6644	Veeras	4ys/Mc	9100	62	32	6	10600	54	41	6	6	15	4	12	11.3	12	Nil	Nil	Nil	Nil	Nil	N
6	9921s	Prajan	4ys/Mc	6800	48	44	8	8700	52	43	5	6	18	5	12	11.7	12.5	Nil	Nil	Nil	Nil	Nil	N
7	9720	Sanjana	4ys/Fc	7300	52	41	7	8900	55	40	5	4	10	3	10	11.1	11.6	Nil	Nil	Nil	Nil	Nil	N
8	7745	Sagithya	4ys/Fc	8500	57	35	8	10100	53	42	5	6	15	5	13	10.7	11.5	Nil	Nil	Nil	Nil	Nil	N
9	7414	Devmadhavan	5ys/Mc	12600	62	30	8	12100	54	41	5	15	25	10	19	12.9	13.2	Nil	Nil	Nil	Nil	Nil	N
10	238	Ashwin Karthick	5ys/Mc	11700	44	47	9	11600	52	42	6	7	15	6	10	12.1	13	Nil	Nil	Nil	Nil	Nil	N
11	562	Ganesh Kumar	5ys/Mc	11400	80	12	8	11500	58	38	4	6	15	5	12	12.7	13	Nil	Nil	Nil	Nil	Nil	N
12	5981	Kaanishka	5ys/Fc	11500	27	66	7	11000	51	44	5	5	12	4	10	11.3	12	Nil	Nil	Nil	Nil	Nil	N
13	7617	Priyadarshini	6ys/Fc	10800	53	41	6	10900	51	43	5	12	20	10	15	11.6	12.5	Nil	Nil	Nil	Nil	Nil	N
14	5114	Harifi	6ys/Fc	8100	42	48	10	9600	51	43	6	2	6	2	5	11.5	12.1	Nil	Nil	Nil	Nil	Nil	N
15	8102	Aswin	6ys/Mc	11100	52	39	9	10900	50	44	6	18	26	15	20	11.8	12.3	Nil	Nil	Nil	Nil	Nil	N
16	5694	Srinivedha	6ys/Fc	11100	58	36	6	11000	55	41	4	3	5	2	4	13.1	13.2	Nil	Nil	Nil	Nil	Nil	N
17	7540	Sharon	6ys/Mc	11100	48	44	8	10900	52	43	5	12	20	9	16	12.2	13	Nil	Nil	Nil	Nil	Nil	N
18	1752	Akash	6ys/Mc	16700	64	28	8	11600	59	36	5	8	15	6	10	12.6	13	Nil	Nil	Nil	Nil	Nil	N
19	2172	Nitish	7ys/Mc	11900	65	30	5	11600	56	40	4	2	7	2	5	13	13.2	Nil	Nil	Nil	Nil	Nil	N
20	5795	Sridhar	7ys/Mc	9000	31	61	8	10100	53	42	5	3	10	2	8	11.8	12.5	Nil	Nil	Nil	Nil	Nil	N

SNO	OPNO	Name	Age/ Sex	Haematological Analysis														URINE ANALYSIS					
				BEFORE TREATMENT				AFTER TREATMENT								HB(gms%)							
				TC(Cu)	DC			TC	BT					AT		BT	AT	BT			AT		
					P%	L%	E%		P%	L%	E%	1/2hr	1hr	½ hr	1hr			ALB	SUG	DEP	ALB	SUG	Dep
21	3754	Keerthana	7ys/Fc	13500	65	29	6	12900	59	37	4	4	8	2	5	10.8	11.2	Nil	Nil	Nil	Nil	Nil	N
22	3847	Shakilaban	7ys/F	12400	73	22	5	11900	57	39	4	0	0	0	0			Nil	Nil	Nil	Nil	Nil	N
23	3869	Banbalan	8ys/Mc	13000	80	16	4	12000	50	45	5	9	15	7	10	11.8	12	Nil	Nil	Nil	Nil	Nil	N
24	6650	Nirekha	81\2ys/Fc	13600	66	30	4	12800	55	31	4	12	22	10	15	13	13	Nil	Nil	Nil	Nil	Nil	N
25	1320	Bhavadarini	9ys/Fc	8300	64	27	9	9600	59	35	6	15	28	10	20	12	12.5	Nil	Nil	Nil	Nil	Nil	N
26	2702	Rithika	9ys/Fc	11000	48	43	9	11100	50	44	6	4	15	2	10	11.5	11.7	Nil	Nil	Nil	Nil	Nil	N
27	4524	Swetha	9ys/Fc	9500	58	34	8	10100	54	40	6	12	32	10	29	11.5	11.8	Nil	Nil	Nil	Nil	Nil	N
28	5636	Karthick	91\2ys/Mc	11600	75	20	5	11800	59	36	5	5	15	3	10	13.1	13	Nil	Nil	Nil	Nil	Nil	N
29	9564	Udhya Saravanan	9ys/Mc	8700	59	35	6	10000	54	41	5	4	10	2	5	12.7	13.4	Nil	Nil	Nil	Nil	Nil	N
30	5052	Naveen	0ys/Mc	8000	61	30	9	9600	56	49	5	5	15	2	10	13.6	13.6	Nil	Nil	Nil	Nil	Nil	N
31	3958	Gunapriya	10ys/Fc	8100	60	34	6	10100	54	42	4	10	25	6	18	12.7	13	Nil	Nil	Nil	Nil	Nil	N
32	6358	Surendar	10ys/Fc	7400	50	43	7	8600	56	40	4	4	20	3	15	13.3	13.2	Nil	Nil	Nil	Nil	Nil	N
33	3256	Sanjana	10ys/Fc	7000	52	39	9	8200	55	40	5	10	25	9	20	13.6	13.4	Nil	Nil	Nil	Nil	Nil	N
34	5709	Abi	11ys/Fc	9100	50	41	9	10100	56	39	5	7	18	5	15	13.0	13.3	Nil	Nil	Nil	Nil	Nil	N
35	9963	Rithika	11ys/Fc	8000	45	46	9	9200	54	40	6	5	12	4	10	13.2	13.3	Nil	Nil	Nil	Nil	Nil	N
36	398	Akshaya	11ys/Fc	8700	59	34	7	9600	56	39	5	5	12	3	9	14.9	14.5	Nil	Nil	Nil	Nil	Nil	N
37	6769	Charles	12ys/Mc	7200	60	34	6	8600	50	46	4	20	45	15	38	14.4	14.5	Nil	Nil	Nil	Nil	Nil	N
38	2261	Kalaiselvan	12ys/Mc	8900	53	39	8	9200	55	40	5	10	24	8	19	14.2	14.4	Nil	Nil	Nil	Nil	Nil	N
39	5690	Sarvendiran	12ys/Mc	7200	49	42	9	8900	51	43	6	12	20	10	18	13.5	14	Nil	Nil	Nil	Nil	Nil	N
40	5640	Sansi	12ys/Mc	5300	46	45	9	6700	50	45	5	3	7	2	14.35		14.5	Nil	Nil	Nil	Nil	Nil	N

TC –Total Count ,DC-differntial count,P-polymorphs,L-iymphocyte,E-eosinophil,M-Monocyte,Hb –Haemoglobin, ESR-Erythrocyte sedimentation rate,Alb-Albumin,Sug-Sugar,Dep-Deposits

DISCUSSION

DISCUSSION

Neer kana maantham is a most common, repeated disease of the children mainly affecting the upper respiratory tract with or without inflammation The disease is characterized by cough, Running nose, fever, Malaise, Diarrhoea and lack of appetite.

In this study, 40 cases were selected according to the proforma with undergone investigation and treated with the trial drug OMA KUDINEER for 7 days with after treatment investigation in the OPD of PG-Dept of Kuzhanthai Maruthuvam, Govt. Siddha Medical College attached to Arignar Anna Hospital of Indian Medicine,Chennai-106. The data were collected and prognosis of the disease with the trial drug was clearly observed.

This study evaluate the effect of OMA KUDINEER" on NEER KANA MAANTHAM (Acute nasopharyngitis).

The observations are described here

1. Age Distribution

According to children's age under 2-3years of age group were 10%, 4-6 years were 35%, 7-10 years were 37.5%, 11-12 years were 17.5% respectively. Hence this study reveals that Neer kana mantham was prevailed more in 7-10 years children.

2. Gender Distribution

Among the 40 cases for this present study, 21 (52.5%) children were male and 19(47.5%) children were female. According to modern theory there is no apparent gender prediction

3. Family History

According to family history, 8 (20%) cases were reported positive family history,and 32 (80%) cases have negative family history. Hence family history may impact on Neer kana maantham.

4. Socio Economic status

Regarding socio-economic status, 19 (47.5%) cases were belong to poor status,16 (40%) cases were belong to middle class and 5 (12.5%) cases belong to high class. The highest incidence was observed in poor class children due to poor hygiene,

malnutrition, exposure to polluted environment lower their immune response, so the poor children are more prone to the disease.

5. Uyir Thathukkal

Disturbance of Vatham

In 40 cases, among 10 types of Vatham, Vyanan,Udhanan, Samanan and Kirukaran are affected. Udhanan and Kirukaran are affected in 100% of cases, Vyanan is affected in 5% cases and Samanan is affected in 15%cases.

Disturbance of Pitham

In 40 cases, among 5 types of pitham,Anal pitham is affected in 87.5% cases, ranjaga pitham is affected in 20% cases and saathaga pitham is affected in 25% cases.

Disturbance of Kabam

In 40 cases, among 5 types of kabam,Avalambakam is affected in 100% cases and Klethakam is affected in 25% cases.

6.Udarthathukkal

In Udarthathukkal, Saaram was affected in all 100% cases and Senneer was affected in 20% cases .

7.Ennvagai Thervugal

Among 40 cases, Naa is affected in 25% cases,Niram is affected in 20%, Vizhi is affected in 20% cases ,sparism is affected in 27.5% cases and the Naadi felt among 40 cases were vathapitham in 40% cases, vathakabam in 25% cases and pithakabam in 35% cases.

8. Neikuri

Among 40 cases, Vatha neer was observed in 60% cases, Pitha neer was observed in 27.5% cases, Kaba neer was observed in 7.5% cases.

9. According to Paruvakaalam

Regarding Paruvakaalam among 40 cases, 5% cases were reported in Koothir kaalam and Elavenil Kaalam, 15% cases were reported in Munpani kaalam, 55% cases were reported in Pinpani kaalam and 20% cases were reported in Muduvenil kaalam respectively.

10. Distribution of Nilam

All the 40 cases reported were from surroundings of Chennai which belongs to Neithal nilam

11. Clinical Presentation

Out of 40 patients, before treatment all the 40 patients had 100% of cough, 100% of Running nose, 27.5% of fever and10% of Malaise. After treatment most of the patients were relieved from the symptoms of cough, fever, running nose and malaise. Improvement in appetite is increased in most of cases additionally.

12. Phytochemical analysis

The Phytochemical analysis of the trial drug shows that the drug contains iron ,chloride, Alkaloids ,Flavonoids, Carbohydrates, tri terpenoids, phenol, glycosides, Tannins and proteins .

13. Toxicity study of the drug

Acute toxicity study of the trial drug was carried out in Wister Albino rats reveals that the drug has no adverse effects, so it is safe for human beings.

14. Physicochemical analysis

Moisture content of the drug is 1.1%.

PH of the drug is 6,

Ash value-9.98%

15.Bio Chemical Analysis:

Biochemical analysis of the drug showed the presence of chloride, iron and zinc.

16. Pharmacological analysis:

Pharmacological analysis showed the drug has convincing Anti-inflammatory action and showed no Anti-microbial activities against both gram positive and gram negative micro-organism.

17. Statistical Analysis

The preclinical studies of trial medicine statistically analyzed and showed significant result.

18. Results

The outcome of this study showed encouraging results. Among the 40 patients good improvement observed in 80%, moderate improvement in 15% and mild improvement in 5% and no adverse events observed clinically during the course of treatment.

SUMMARY

SUMMARY

The disease Neer Kana Mantham was taken for the clinical study with Oma kudineer as internal medicine. For the clinical study, 40 patients were selected based on Inclusion and Exclusion criteria. The study is conducted after the drug being screened by the Screening committee and the trial is also approved by the Institutional Ethical Committee (IEC). Animal studies are carried out after obtaining proper permission from the Institutional Animal Ethical Committee (IAEC). Hence the study is safely executed on human volunteer patients and there was no adverse drug reactions noted during the study period. 40 children with Neer kana maantham diagnosed clinically treated in out patient department of Arignar Anna Hospital of Indian Medicine,Chennai-106. They were observed for clinical improvement, laboratory investigation done and treated with trial drug.

I like to summarize this study with the following highlights.

- The efficacies of the trial drug Oma kudineer were studied and observed in this study.
- Clinical diagnosis of Neer kana maantham was done on the basis of clinical features described in Bala vagadam(siddha pediatric book)
- The cost of the trial medicines are low, comparatively economic. These drugs are easily available and the dosage is also convenient.
- The potency of the trial drug were studied by phytochemical analysis, physico chemical analysis and pharmacological analysis.
- Phytochemical analysis of the trial drug reveals that the presence of Alkaloids, flavonoids, glycosides, carbohydrates, triterpnoids, tannins, phenols& proteins.
- The physico chemical analysis of the trial drug shows the PH-6, and Ash value - 2.44% , So it shows the safe and effectiveness of the drug.
- The pharmacological analysis of the drug reveals that it possesses convincing Anti-inflammatory property.
- Among the 40 cases treated, 80% cases had shown Good improvement, 15% cases had shown Moderate improvement, 5% had shown Mild improvement.
- Observation made during the clinical study showed that the trial drug was clinically effective and has no adverse effect.

CONCLUSION

CONCLUSION

Neer kana Maantham is a common disease in children and mainly caused by derangement of kaba kuttram. In this clinical study **Oma kudineer** was taken as Internal drug respectively.The deranged kabam is settled down by the kaarppu suvai in the trial medicine there by the medicine acts as Ethirurai maruthuvam to cure the disease.Toxicological studies showed **no acute toxicity**. The drug has got **Anti inflammatory** activity .The cost of the trial medicines are low .During the clinical study no adverse events were observed.

The clinical study confirms the efficacy of the trial drugs by reducing the clinical signs and symptoms like Cough, cold, running nose ,Fever, and loss of appetite. Clinical study results found to be Good in 80% cases, Moderate in 15% cases, and Mild in 5% cases .The Clinical trial conducted in selected patients was satisfactory and encouraging. The trial medicine is **effective** for **Neer kana Maantham** in children. Through this study, the effectiveness of trial drug is confirmed and re-established by the author and concluded that the TRIAL drug "**OMA KUDINEER**" is effective in treatment of **acute naso pharyngitis** (common cold).

ANNEXURES

CERTIFICATES

GOVERNMENT SIDDHA MEDICAL COLLEGE
Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-4/020/2015

Protocol title: A CLINICALSTUDYON NEER KANA MANTHAM (ACUTE NASO PHARYNGITIS) WITH THE EVALUATION OF SIDDHA DRUG OMA KUDINEER.
Principal Investigator: DR.D.S.LAVANYA
Name & Address of Institution: Government Siddha Medical College, Arumbakkam, Chennai-106
☑ New Review ☐ Revised Review ☐ Expedited Review
Date of review (DD/MM/YY): 26-03-2015 Date of Previous Review, If Revised Application:
Decision of the IEC ☑ Recommended ☐ Recommended with suggestions ☐ Revision ☐ Rejected
Suggestions / Reasons / Remarks: Change one palam into 35gm as per siddha formulary
Recommended for a period of 1 year from date of completion of preclinical studies:

Please Note:

- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.

26/3/15.

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V.Banumathi
Member Secretary

INSTITUTIONAL ETHICS COMMITTEE

Date:

Sub: IEC review of research proposals.

Ref:Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
DR.P.JEYAPRAKASH NARAYANAN M.D(S)., Chairman		
DR.V.BANUMATHI M.D(S)., Member Secretary		
DR.N.KABILAN M.D(S)., Clinician- Siddha	✓	26/3/15
DR.P.SATHIYA RAJESWARAN M.D(S)., Clinician- Siddha	✓	26/3/15
DR.G.AADINAAATH REDDY,M.Pharm, Ph.D., Pharmacologist	✓	Aadinaath 26/03/15
DR.S.THILAGAVATHY Msc.,Ph.D., Social Scientist	✓	26/3/15
DR.T.MAHALAKSHMI M.A.,Ph.D., Linguistic Expert	✓	T.M 26.03.15
DR.P.VIDYA M.B.B.S., DMRD., Modern Medicine Expert	✓	26/3/15
MR.P.SARAVANAN., Pupilc Person	✓	

24/3/15

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V.Banumathi
Member Secretary

The Tamil Nadu Dr.M.G.R.Medical University

69,Anna Salai,Guindy,Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs... Dr. S. Saranya .....

for participating as ~~Resource Person~~ / Delegate in the Eighteenth Workshop on

" RESEARCH METHODOLOGY & BIOSTATISTICS "

FOR AYUSH POST GRADUATES & RESEARCHERS

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University from 20th to 24th July 2015.

Dr.N.KABILAN, M.D (Siddha)
READER,DEPT.OF SIDDHA

Prof **Dr.P.ARUMUGAM,** M.D.
REGISTRAR i/c

Prof **Dr.D.SHANTHARAM,** M.D., D.Diab.
VICE - CHANCELLOR

The Tamil Nadu Dr.M.G.R. Medical University

#69, Anna salai, Guindy, Chennai-600 032.

This certificate is awarded to

Dr./Mr./Ms. D.S. LAVANYA

for participating as ~~Resource Person~~ / Delegate in the First Workshop on

"Pre-clinical Studies in Research"

for Faculties & PG students of ASU Systems

Organised by the Department of Siddha,

The Tamil Nadu Dr. M.G.R. Medical University on 16.12.2014

Dr. N. KABILAN M.D. (Siddha)
Reader, Dept. of Siddha

Dr. JHANSI CHARLES, M.D.
Registrar

Prof. Dr. D. SHANTHARAM, M.D., D.Diab.,
Vice-Chancellor

सिद्ध केंद्रीय अनुसन्धान संस्थान
(सी सी आर एस., चेन्नई, आयुष मंत्रालय, भारत सरकार)
अण्णा सरकारी अस्पताल परिसर, अरुम्बाक्कम, चेन्नई - 600106

SIDDHA CENTRAL RESEARCH INSTITUTE
(Central Council for Research in Siddha, Chennai,
Ministry of AYUSH, Government of India)
Anna Govt. Hospital Campus, Arumbakkam, Chennai - 600106
E-mail: crisiddha@gmail.com Phone: 044-26214925, 26214809

24th May 2016

CERTIFICATE

Certified that the drugs submitted for identification by Dr. D.S. Lavanya, PG 2nd year, Department of Kuzhanthai maruthuvam, Government Siddha Medical College, Arumbakkam, Chennai - 600 106, are identified as

1. Poondu	-	*Allium sativum* L. (Bulb)
2. Omam	-	*Trachyspermum ammi* (L.) Sprague (Fruit) Syn. *Carum copticum* (L.) Link.
3. Milagu	-	*Piper nigrum* L. (Fruit)
4. Thippili	-	*Piper longum* L. (Fruit)

Sasikala Ethirajulu

Sasikala Ethirajulu
Consultant (Pharmacognosy)

24/5/16

P.Sathiyarajeswaran
Assistant Director Incharge

CERTIFICATE

This is to certify that the project entitled "**ACUTE AND SUB-ACUTE TOXICITY EVALUATION OF OMA KUDINEER IN RATS.**" has been approved by the Institutional Animal Ethics Committee of Sathyabama University, Chennai.

IAEC Approval No.: **SU/CLATR/IAEC/VII/040/2016**
Principal Investigator:Dr. D. S. Lavanya
Animal Sanctioned: *Rattus norvegicus* / Wistar Albino rats
Female:6; Total: 6 (Six)
Date: 05.10.2016

DR.R.SELVARAJ
Member Secretary

DR.R.ILAVARASAN
CPCSEA Nominee

CLINICAL RESEARCH & HOSPITALS (P) LTD

National Conference on

HERBAL MEDICINE AND ETHNOPHARMACOLOGY

Date: 06.04.2017; Venue: TICEL Biopark.

*This is to certify that ~~Ms./Mr.~~/Dr. ....D.S. LAVANYA.....from ..DEPT. OF. PEDIATRICS..... ..GOVT. SIDDHA. MEDICAL. COLLEGE, .CHENNAI..... attended the National Conference on "**Herbal Medicine and Ethnopharmacology**" conducted in V.S. Clinical Research & Hospitals (P) Ltd., Chennai, Tamil Nadu. He/She presented a paper/poster in the topic ... SIDDHA. ... HERBS. ON. ANTI-OBESITY. TREATMENT - REVIEW.....*

T. Mathangi

Dr. T. Mathangi
Scientist & Coordinator

Dr. L. Lokoranjan
Chairman & Managing Director

BIO-CHEMICAL ANALYSIS

BIOCHEMICAL ANALYSIS OF OMA KUDINEER

PREPARATION OF EXTRACT:

2 gm of Oma kudineer sample is taken in a100 ml beaker and 20 ml of distilled water is added. The solution is boiled for 10 minutes, cooled and then filtered. The filtrate is called extract.

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
1	TEST FOR ACID RADICLES		
A	**Test for chloride** : 2ml of extract is added with dilute Nitric acid till the effervescence ceases. Then 2ml of silver nitrate solution is added.	Presence of white Precipitate	Present
B	**Test for phosphate:** 2 ml of the extract is treated with 2 ml of Ammonium molybdate solution and 2 ml of concentrated nitric acid	Absence of Yellow Precipitate	Absent
C	**Test for carbonate:** 2 ml of the extract is treated with 2 ml of Magnesium sulphate solution	Absence of white Precipitate	Absent
D	**Test for sulphide**: 1 gm of the substance is treated with 2 ml of concentrated Hydrochloric acid	Absence of Rotten egg Smelling	Absent
E	**Test for sulphate**: 2ml of the above prepared extract is taken in a test tube.to this add 2ml of 4 % Ammonium oxalate solution.	Absence of white Precipitate	Absent

2	TEST FOR BASIC RADICALS		
A	**Test for copper**: One pinch of substance is made into paste with concentrated Hydrochloric acid in a watch glass and introduced into the non-luminous part of the flame.	Absence of Bluish green colored flame	Absent
B	**Test for iron:** To the 2 ml of extract 2ml of Ammonium thiocyanate solution and 2ml of concentrated Nitric acid is added.	Presence of Blood red colour	Present
C	**Test for zinc**: To the 2 ml of extract Sodium hydroxide solution is added in drops in excess	White precipitate is obtained	Present
D	**Test for calcium**: To the 2 ml of extract Ammonium oxalate solution solution is added	Absence of white precipitate	Absent
E	**Test for magnesium**: To the 2 ml of extract Sodium hydroxide solution is added in drops in excess	Absence of white precipitate	Absent
F	**Test for starch**: 2 ml of extracts treated with weak iodine solution	Absence of white precipitate	Absent
G	**Test for reducing sugar** : 5ml of Benedicts qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 10 drops of the extract and again boiled for 2minutes.The colour changes are noted	Absence of white precipitate	Absent
H	**Test for alkaloids** : 2 ml of the extract is treated with 2ml of Potassium iodide solution.	Presence of red colour	Present
I	**Test for ammonium**: To the 2 ml of extract few ml of Nessler's reagent and excess of Sodium hydroxide solution are added.	Absence of white precipitate	Absent

Inference

The Given Sample Oma kudineer Contains-Acid Radicals-Chloride

Basic Radicals-Iron, Copper

PHYSICO CHEMICAL ANALYSIS

Physicochemical Evaluation

Project ID : NRS/AS/0021/01/2017

Institute : Govt Siddha Medical College

Sample Name : Oma Kudineer

Sample ID : OK

Percentage Loss on Drying

10gm of test drug was accurately weighed in evaporating dish .The sample was dried at 105^{o}C for 5 hours and then weighed.

Percentage loss in drying = Loss of weight of sample/ Wt of the sample X 100

Determination of Total Ash

3 g of test drug was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

Total Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of Acid Insoluble Ash

The ash obtained by total ash test will be boiled with 25 ml of dilute hydrochloric acid for 6mins. Then the insoluble matter is collected in crucible and will be washed with hot water and ignited to constant weight. Percentage of acid insoluble ash will be calculated with reference to the weight of air-dried ash.

Acid insoluble Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of Water Soluble Ash

The ash obtained by total ash test will be boiled with 25 ml of water for 5 mins. The insoluble matter is collected in crucible and will be washed with hot water, and ignite for 15

minutes at a temperature not exceeding 450ºC. Weight of the insoluble matter will be subtracted from the weight of the ash; the difference in weight represents the water soluble ash. Calculate the percentage of water-soluble ash with reference to the air-dried drug.

Water Soluble Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of Alcohol Soluble Extractive

About 5 g of test sample will be macerated with 100 ml of Alcohol in a closed flask for twenty-four hours, shaking frequently during six hours and allowing to stand for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug.

Alcohol sol extract = Weight of Extract/ Wt of the Sample taken X 100

Determination of Water Soluble Extractive

About 5 g of the test sample will be macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, shaking frequently during six hours and allowing to stand and for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weigh. Calculate the percentage of water-soluble extractive with reference to the air-dried drug.

Water soluble extract = Weight of Extract/ Wt of the Sample taken X 100

Determination of pH

About 5 g of test sample will be dissolved in 25ml of distilled water and filtered the resultant solution is allowed to stand for 30 mins and the subjected to pH evaluation

Final Test report

S.No	Parameter	Mean (n=3) SD
1.	*Loss on Drying at 105 °C (%)*	7 ± 2.26
2.	*Total Ash (%)*	9.98 ± 2.44
3.	*Acid insoluble Ash (%)*	3.2 ± 1
4.	*Water Soluble Ash (%)*	13.73 ± 0.61
5.	*Alcohol Soluble Extractive (%)*	15.66 ± 1.59
6.	*Water soluble Extractive (%)*	25.33 ± 2.01
7.	*PH*	6

Reference:

1. India Pharmacopeia I Volume I, Government of India, Ministry of Health and Family welfare, Indian Pharmacopeia commission, 2014.
2. Pharmacopoeial Laboratory for Indian Medicine (PLIM) Guideline for standardization and evaluation of indian medicine which include drugs of Ayurveda, Unani and Siddha systems. Department AYUSH .Ministry of Health & Family Welfare, Govt. of India

PHYTOCHEMICAL ANALYSIS

PHYTOCHEMICAL ANALYSIS

Sample Preparation

Oma Kudineer (OK) was extracted with hydro alcoholic solvent (Methanol: water) 6:4 and the extract was subjected to the following analysis

Test for alkaloids:

Mayer's Test: To the extract, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

1) **Test for coumarins:**

To 1 ml of extract, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

2) **Test for saponins:**

To 1 ml of the extract, 5 ml of water was added and the tube was shaken vigorously. Copious lather formation indicates the presence of Saponins.

3) **Test for tannins:**

To the extract, ferric chloride was added, formation of a dark blue or greenish black color showed the presence of tannins.

4) **Test for glycosides- Borntrager's Test**

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

5) **Test for flavonoids:**

To 0.1ml of the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

6)Test for phenols:

Lead acetate test: The extract was taken; 3 ml of 10% lead acetate solution was added. A bulky white precipitate indicated the presence of phenolic compounds.

7)Test for cardial glycosides:

Keller-Killani Test: Plant extract treated with 2 ml glacial acetic acid containing a drop of FeCl3 .A brown colour ring indicates the presence of positive test.

8)Test for steroids:

To the test solution 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence. It showed the presence of steroids.

9)Test for Quinones:

The extracts were treated separately with Alc. KOH solution. Appearance of colors ranging from red to blue indicates the presence of Quinones.

10)Test for Cyanins

A. Aanthocyanin:

To 2 ml of the leaf extract, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100^{o}C. Formation of bluish green colour indicates the presence of anthocyanin.

B. Betacyanin:

To 2 ml of the leaf extract, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100^{o}C. Formation of yellow colour indicates the presence of betacyanin.

11)Test for Carbohydrates - Benedict's test

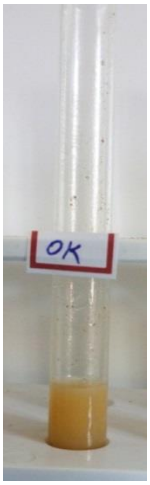
To 0.5 ml of test drug about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

12)Test for terpenoids:

Salkowski test: 5ml of extract was mixed in 2ml of chloroform, and concentrated sulphuric acid was carefully added to form a layer. A reddish brown colouration of the interface indicates the presence of terpenoids.

RESULTS

Test for Alkaloid



Test for Coumarins

Test for Saponins

Test for Tanins

Test for Glycosides

Test for Flavonoids

Test for Phenols

Test for Cardiac Glycosides

Test for Steroids

Test for Terpenoids

Test for Quinones

PROTEINS

Test for Anthocyanins

CARBOHYDRATES

Result Analysis

PHYTOCOMPONENTS	OK
ALKALOIDS	+
FLAVONOIDS	+
GLYCOSIDES	+
STEROIDS	-
CARBOHYDRATES	+
TRITEREPNOIDS	+
COUMARINS	-
PHENOLS	+
CARDIAC GLYCOSIDES	-
TANNINS	+
SAPONINS	-
PROTEINS	+
ANTHOCYANIN	-
BETACYANIN	-
QUINONES	-

+ Indicates positive

- Indicates Negative

Reference

Brain KR, Turner TD. The Practical Evaluation of Phytopharmaceuticals. Bristol: Wright- Scientechnica; 1975:36-45

TLC AND HPTLC ANALYSIS REPORT

TLC Analysis Report

Project ID : NRS/AS/0021/01/2017

Institute : Govt Siddha Medical College

Sample Name : Oma Kudineer

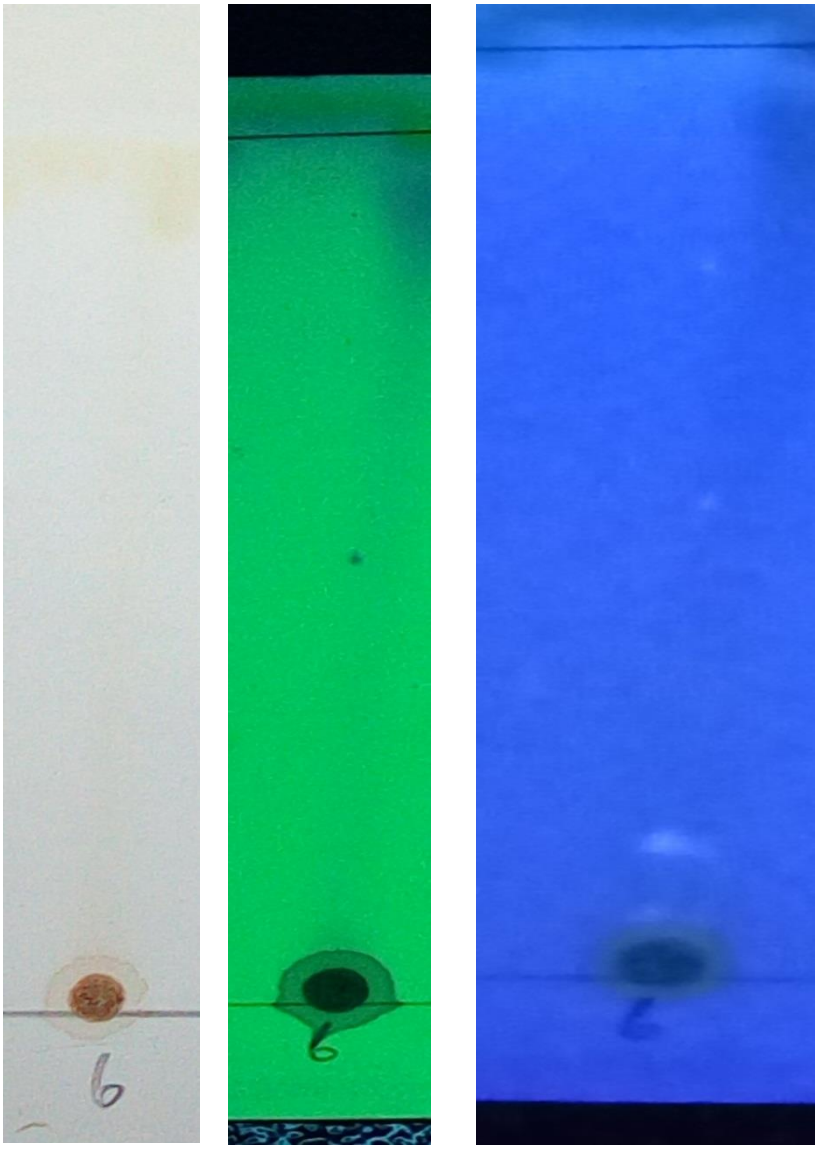
Sample ID : OK

TLC Analysis

Test sample OK was subjected to thin layer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 7X6 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil. Micro pipette were used to spot the sample for TLC applied sample volume 10-micro liter by using pipette at distance of 1 cm at 5 tracks. In the twin trough chamber with different solvent system Ethyl acetate: Methanol: Water (100:13.5:10) After the run plates are dried and was observed using visible light Short-wave UV light 254nm and light long-wave UV light 365 nm

Sample Spotting

Visible Short UV Long UV



Reference

Lukasz Komsta, Monika Waksmundzka-Hajnos, Joseph Sherma . Thin Layer Chromatography in Drug Analysis . CRC Press, Taylor and Francis.

High Performance Thin Layer Chromatography Analysis

HPTLC method is a modern sophisticated and automated separation technique derived from TLC. Pre-coated HPTLC graded plates and auto sampler was used to achieve precision, sensitive, significant separation both qualitatively and quantitatively. High performance thin layer chromatography (HPTLC) is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. HPTLC method offers high degree of selectivity, sensitivity and rapidity combined with single-step sample preparation. In addition it is a reliable method for the quantitation of nano grams level of samples. Thus this method can be conveniently adopted for routine quality control analysis. It provides chromatographic fingerprint of phytochemicals which is suitable for confirming the identity and purity of medicinal plant raw materials.

Chromatogram Development

It was carried out in CAMAG Twin Trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analysed. After elution, plates were taken out of the chamber and dried.

Scanning

Plates were scanned under UV at 366nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print was developed for the detection of phytoconstituents present in each extract and Rf values were tabulated.

Reference

1. Wagner H. Plant Drug Analysis. A thin Layer chromatography Atlas.2nd ed. Heidelberg: Springer-Verlag Belgium; 2002:305, 227.

HPTLC Chromatographic condition

Sample : OK

Derivatization Solvent :Anisaldehyde

Stationary phase : Silica gel GF_{254}

Mobile phase : Chloroform : n-butanol: methanol: water: Acetic acid (4:1:1:0.5:0.5)

Scanning wavelength : 366 nm

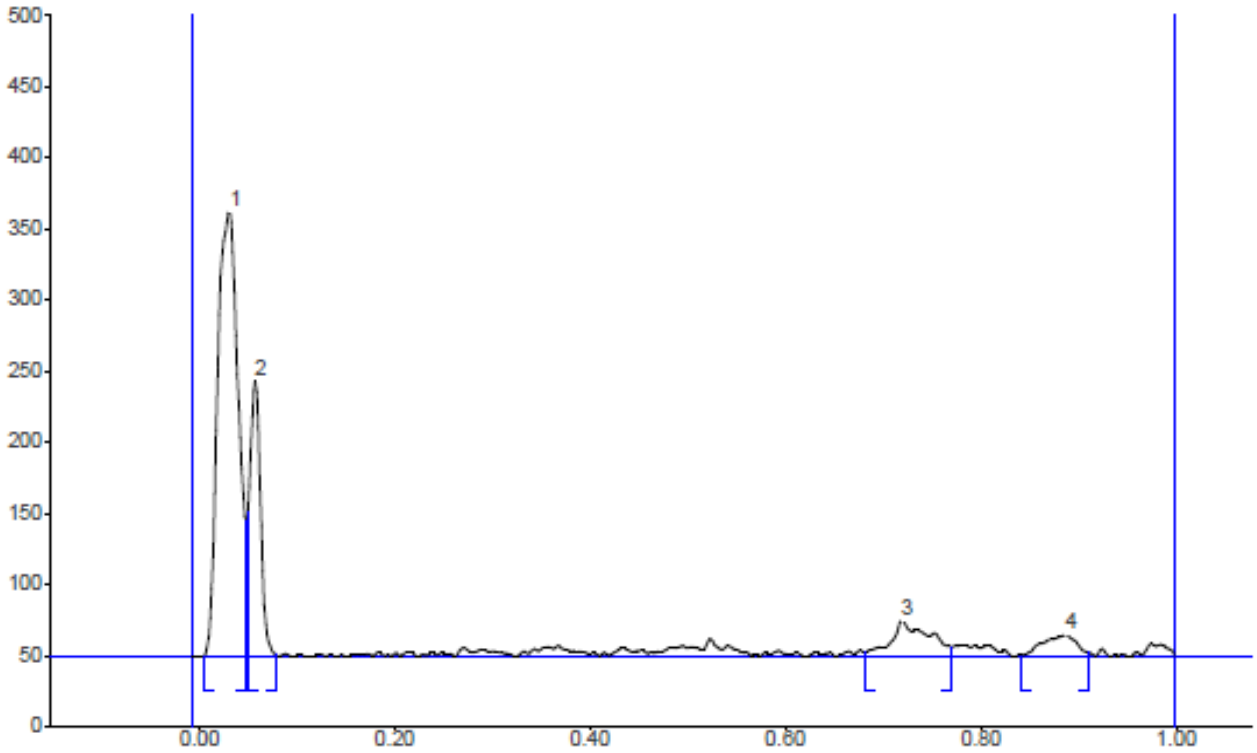
Sample concentration : 10mg/ml

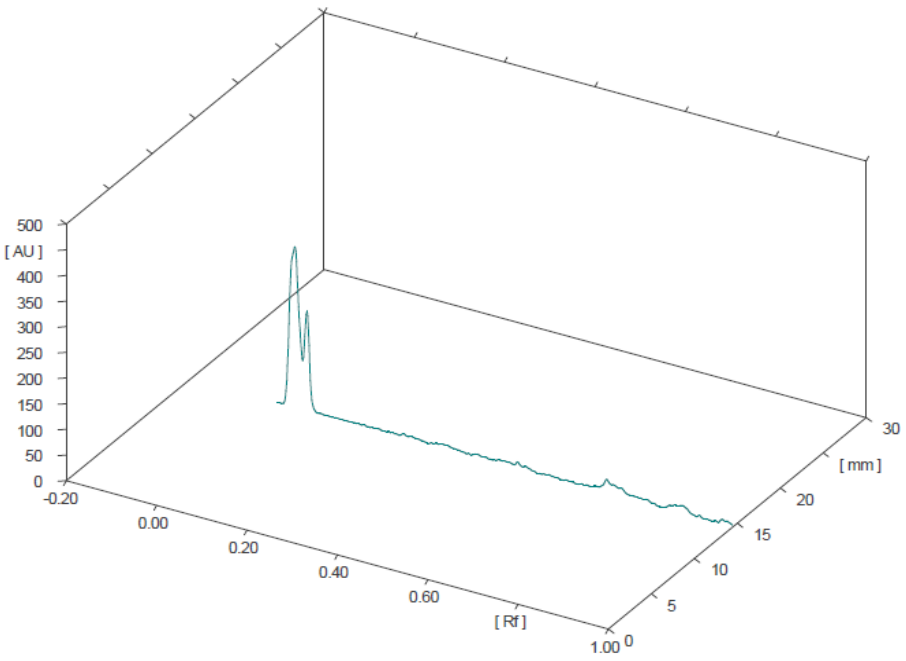
Applied volume : 5 µl

Application mode : CAMAG HPTLC

TLC Histogram

HPTLC CHROMATOGRAM OF OK





Peak Table of HPTLC finger printing of OK

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.00	0.1	0.03	312.5	57.22	0.05	94.3	4987.0	64.64
2	0.05	101.8	0.06	193.6	35.44	0.08	0.5	1634.4	21.18
3	0.68	2.9	0.72	25.0	4.58	0.77	6.3	712.1	9.23
4	0.84	0.4	0.89	15.1	2.76	0.91	2.4	381.5	4.94

STERILITY TEST

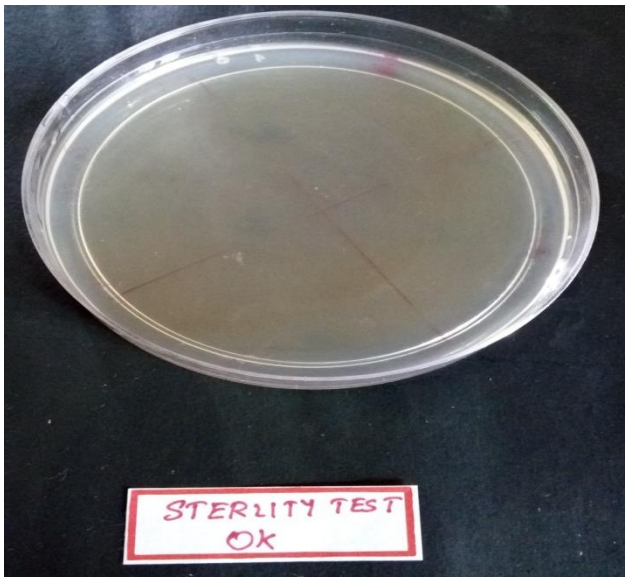
STERILITY TEST BY POUR PLATE METHOD

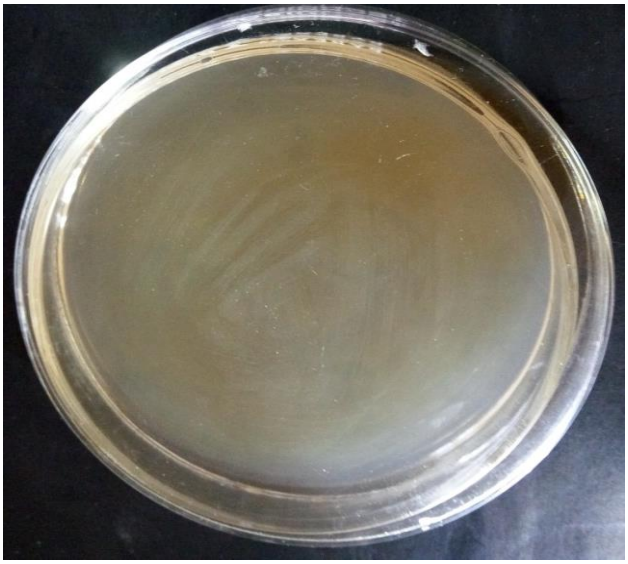
Objective

The pour plate techniques were adopted to determine the sterility of the product. Contaminated un sterile sample (formulation) when come in contact with the nutrition rich medium it promotes the growth of the organism and after stipulated period of incubation the growth of the organism was identified by characteristic pattern of colonies. The colonies are referred to as Colony Forming Units (CFUs).

Methodology

About 1ml of the test sample was inoculated in sterile petri dish to which about 15 mL of molten agar 45^{o}C were added. Agar and sample were mixed thoroughly by tilting and swirling the dish. Agar was allowed to completely gel without disturbing it. (about 10 minutes). Plates were then inverted and incubated at 37^{o} C for 24-48 hours. Grown colonies of organism was then counted and calculated for CFU.





Observation

No growth was observed after incubation period. Reveals the absence of specific pathogen

Result

No growth / colonies were observed in any of the plates inoculates with the test sample.

Test	**Specification**	**Result**	**Method**
E-coli	Absent	Absent	As per AYUSH specification
Salmonella	Absent	Absent	
Staphylococcus Aureus	Absent	Absent	
Pseudomonas Aeruginosa	Absent	Absent	

HEAVY METAL ANALYSIS REPORT

ICP-MS- Heavy Metal Analysis Report

ICP-MS

Inductively Coupled Plasma Mass Spectrometry (ICP-MS): ICP-MS is a type of mass spectrometry that is highly sensitive and capable of the determination of a range of metals and several non-metals at concentration below one part in 1012 (parts per trillion). Samples are decomposed to neutral elements in high temperature argon plasma and analyzed based on their mass to charge ratios. It is an automated, simple and unique quantitative and qualitative analysis. It measures elemental isotopes ratio.

Procedure

Digestion of sample is carried out by transforming 2.5 ml of the sample into a closed beaker and 5 ml of concentrated HNO_3 was added and digested to near dryness. 16 M nitric acid was further added each time to the sample and digested until the clear solution was obtained. 5ml of 12 M Hydrochloric acid was added to ensure complete digestion .The digested solution was cooled to room temperature and made to the final volume of 100 ml with deionized water. Sample solutions were then filtered through membrane (0.45micron) filter. Finally, the digested samples were used for metal analysis using inductively coupled plasma Mass Spectrometry (Perkin Elmer DRC-e Model) .Each sample was digested in triplicate. A blank solution was also prepared in a similar manner.

Machine Model: **Agilent 7700 ICPMS**

Sample ID: OK

Element	Concentration (mg/L)	Upper Limit (mg/L)
Cadmium (Cd)	**BDL**	0.299

BDL- Below Detective Level

Reference

1. Smille TJ and Khan IA, A Comprehensive approach to Identifying and authenticating Botanical Products, *Clinical Pharmacology and therapeutics*. 2010; 87(2): 175-186.
2. Limmatvapirat CJ, Charoenteeraboon, Phaechamud T. Simultaneous analysis of eleven heavy metals in extracts of Sonneratia caseolaris (L.) Engl. By ICP-MS. *Res. J. Pharm., Biol. Chem.Sci*.2012; 3:744-50.

TOXICITY STUDY

Name	Dr. D.S.LAVANYA
IAEC	SU/CLATR/IAEC/VII/040/2016
Name of the Formulation	***Oma Kudineer***
Abbreviation	OK

Project Report on Toxicity Profiling of *Oma Kudineer*

ACUTE TOXICITY STUDY

Acute toxicity study of the study drug ***Oma Kudineer*** was carried out as per OECD guideline (Organization for Economic Co-operation and Development) Guideline-423.

Animal

Healthy adult Wistar albino rat weighing between 170-200 g were used for the study. The animals were housed in poly propylene cages and were kept in well ventilated with 100% fresh air by air handling unit (AHU). A 12 light / dark cycle were maintained .Room temperature was maintained between 22 $\pm$ 2^0 C and relative humidity 50–65%. They were provided with food (Sai feeds, Bangalore, India) and water *ad libitum*. All the animals were acclimatized to the laboratory for 7 days prior to the start of the study.

The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India.

Acute toxicity Study

Acute toxicity study will be carried out in accordance with OECD guideline 423 [1]. The animals were fasted overnight with free access to water. The study was conducted with single oral dose administration of ***Oma Kudineer***.

IAEC SU/CLATR/IAEC/VII/040/2016

Animal Grouping

One group consist of 6 female rats were used for this study. The dose utilized for evaluation of acute toxicity study is about 2000 mg/kg higher than that of the therapeutic dose.

Animal Grouping

GROUP I : Animals received Test drug 2000 mg/kg (p.o)

The animals were fasted overnight (12- 16 hrs) with free access to water. The study was conducted with single oral administration of study drug *Oma Kudineer* 2000mg/kg (p.o). The animals were observed continuously for first 72 h and then 14 days for emerging signs of behavioral changes, body weight changes and for mortality.

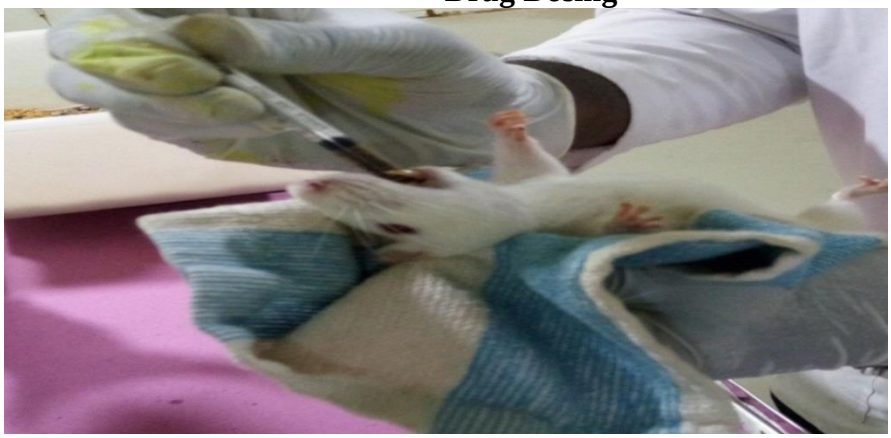
Occurrence of toxicity in animals were observed continuously for the first 4 to 24 h and observed periodically for the next 14 days. Observation includes the change in skin, fur, eyes and mucus membrane. Appearance of C.N.S,C.V.S and A.N.S related toxicity such as tremors, convulsions, sedation, steric behavior, respiratory distress, cardiovascular collapse, response to sensory stimuli, salivation, diarrhea, lethargy, sleep, coma and mortality were observed with special attention.

Body weight was recorded periodically. At the end of the experiment all animals were subjected for gross necropsy and observed for pathological changes.

Statistical analysis

The statistical analysis was carried by one way ANOVA (GRAPH PAD PRISM 5 computer program). Results were expressed as mean ± standard error .A statistical comparison was carried out using the Dunnet's test for the control and treatment group.

Drug Dosing



Fecal Pellet Analysis

Methodology

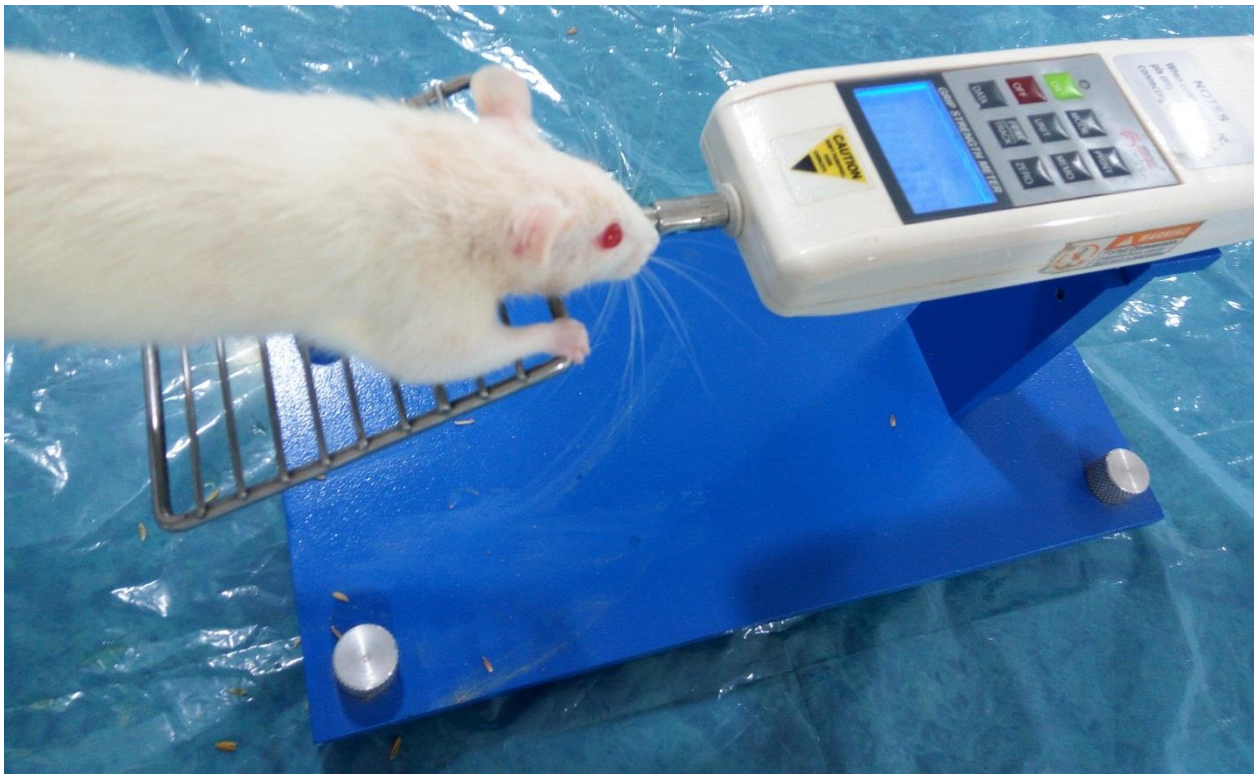
Rats of control and treatment group were allowed to explore to open field on clean and sterile Stainless steel tray. The collected pellets were analyzed for consistency, color, Shape, Presence of blood cells etc

Acute Toxicity Study

Analysis	**Group I**
Consistency	Soft Pasty
Shape	Irregular
Colour	Pale brownish
Mucous Shedding	Absence
Blood Cells	Absent
Signs of Infection	None Observed

Muscle Grip Strength Analysis

The grip strength test is a simple non-invasive method designed to evaluate rat muscle force in vivo. Rats of control and drug treated group was allowed to hold the pull bar with both the hind limbs firmly then the animal was gently pulled back with the tail until the animal lost the grip toward the bar. The procedure was repeated to get the average value. Muscle grip ness of the drug treated group was compared to that of the control rat to ensure the change in coordination.



Metabolic Cage for Urine Collection

Rat of control and treatment group was placed individually in metabolic cage with free access to feed and water. Urine dropping from the animal was collected using specialized wire mesh system fixed at the base of the cage having provision to trap the fecal pellet mixed with urine sample. The collected urine sample was subjected to analysis with respect to colour, pH, glucose, ketone bodies, pus and blood cells.

RESULTS

Assessment of clinical signs in rats treated with *Oma Kudineer* on Acute toxicity study

Acute	
Parameter	**Group I**
Clinical Signs Parameters for the duration of 14 days	**Test Drug 2000mg/kg**
Number of animals observed	6 Female
Lacrimation	Absence
Salivation	Absence
Animal appearance	Normal
Tonic Movement	Absence
Clonic Movement	Absence
Laxative action	Moderate
Touch Response	Normal
Response to Sound	Normal Response
Response to Light	Normal Response
Mobility	Normal Response
Respiratory Distress	Nil
Skin Color	Normal
Stereotype behaviour	Absence
Piloerection	Absence
Limb Paralysis	Absence
Posture	Normal
Open field behaviour	Normal
Giat Balancing	Normal
Freezing Behaviour	Absent
Sings of Stress and Anxiety	None Observed
Muscular coordination	Normal
Muscle grip	Normal
Sedation	Absence
Social Behavior	Normal
Urine Analysis	No Abnormality
Urine Colour	Yellowish
Urine Ph	6
Urine -Glucose	Absence
Urine -Ketones	Absence
Urine- Bilirubin	Absence
Urine-Blood Cells	Negative
Urine - Pus cells	Negative
Mortality	Nil

Quantitative data on the body weight of rats treated with *Oma Kudineer* in Acute toxicity study

Group I	Before Treatment Weight in Gms	After Treatment Weight in Gms
Mean	179.5	188.8
Std. Deviation	4.80	5.776
Std. Error	1.962	2.358

Values are mean ± S.D (n = 6 per group). Statistical significance carried out using one way ANOVA followed by Dunnett's test.

Organ Gross Observation of rats treated with *Oma Kudineer* in Acute toxicity study

Treatment Female

Quantitative data on absolute organ weight of rats treated with *Oma Kudineer* in Acute toxicity study

Group I Acute Tox Study	HEART (gms)	LIVER (gms)	KIDNEYS (gms)	SPLEEN (gms)	BRAIN (gms)	LUNG (gms)	STOMACH (gms)	UTERUS & OVARY (gms)
Mean	0.5917	5.182	1.55	0.7	1.517	1.633	0.8333	1.417
Std. Deviation	0.1436	1.022	0.1643	0.1549	0.2317	0.2422	0.2875	0.1329
Std. Error	0.05862	0.4171	0.06708	0.06325	0.09458	0.09888	0.1174	0.05426

Values are mean ± S.D (n = 6 per females) .Statistically done using one way ANOVA followed by Dunnett's test.

Reference

1. OECD Guideline for testing of Chemicals (2001) Guideline 423: Acute Oral Toxicity-Acute Toxic Class Method.

PHARMACOLOGICAL STUDY

In-vitro Anti-Inflammatory Activity by Protein (Albumin) denaturation Assay

Project ID : NRS/AS/0021/01/2017

Institute : Govt Siddha Medical College, Chennai, Tamil Nadu, India

Sample Name : Oma Kudineer

Sample ID : OK

Sample Stock prepared using DD water

Albumin Denaturation Assay Procedure

In-vitro anti-inflammatory activity Oma Kudineer (OK) was studied using albumin denaturation technique. The reaction mixture consisted of bovine serum albumin (5% aqueous solution) and test sample OK at varying concentration ranges from 100 to 500 mcg/ml and standard diclofenac sodium at the concentration of100 mcg/ml of final volume. pH was adjusted by using a small amount of 1N Hydrochloric acid. The samples were incubated at 37°C for 20 min and then heated at 57°C for 3 min. After cooling the sample, 2.5 ml of phosphate buffer solution was added into each test tube. Turbidity developed was measured spectrophoto-metrically at 660 nm, for control distilled water was used instead of test sample while product control tests lacked bovine serum albumin. The experiment was performed in triplicate.

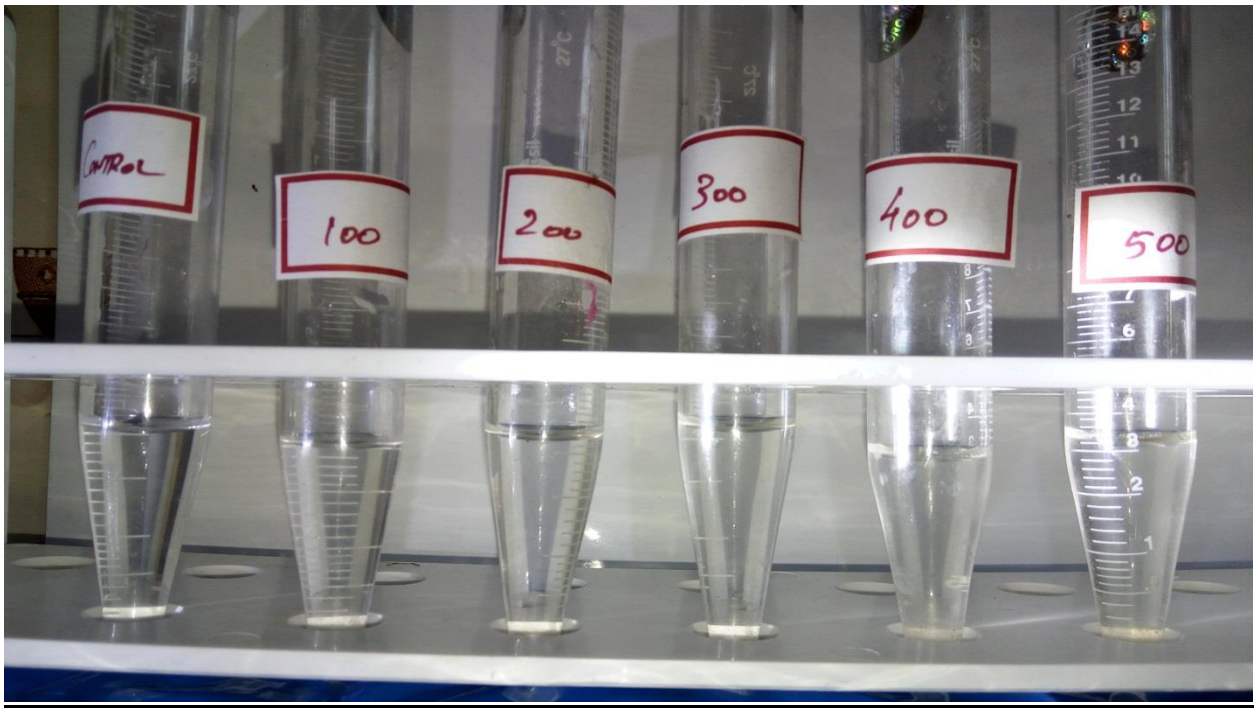
The Percentage protection from denaturation is calculated by using the formulae

$$\left[\frac{(A)_{\text{control}} - (A)_{\text{sample}}}{(A)_{\text{control}}}\right] \times 100.$$

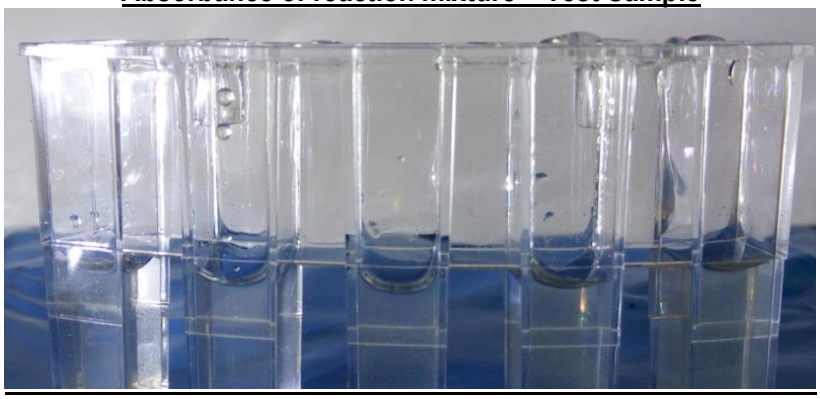
Statistical analysis

Results are expressed as Mean ± SD. The difference between experimental groups was compared by One-Way Analysis Of Variance (ANOVA) followed by Dunnet Multiple comparison test

Preparation of Test and control

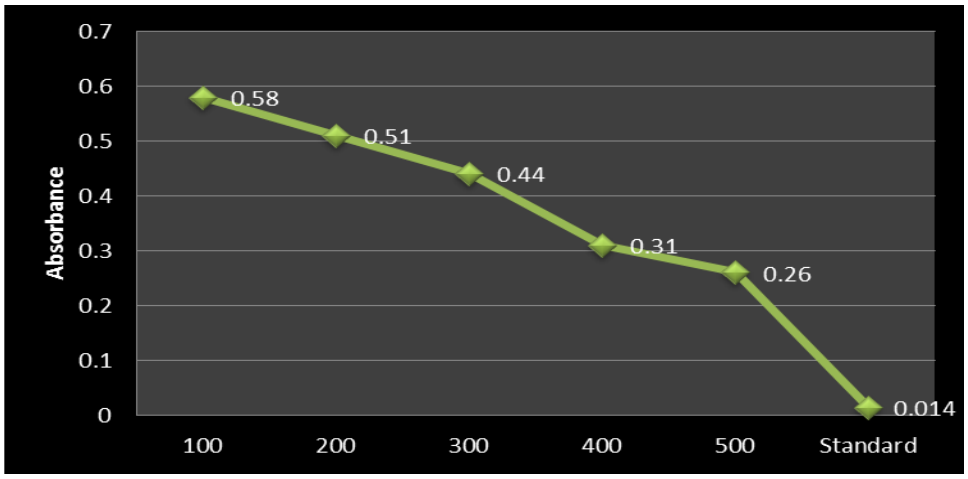


Absorbance of reaction mixture – Test Sample

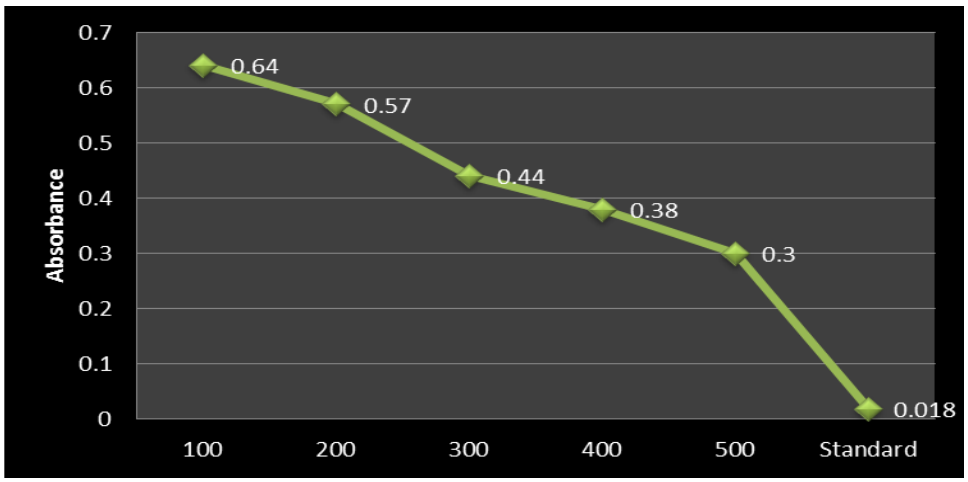


Absorbance of reaction mixture – Control and Standard

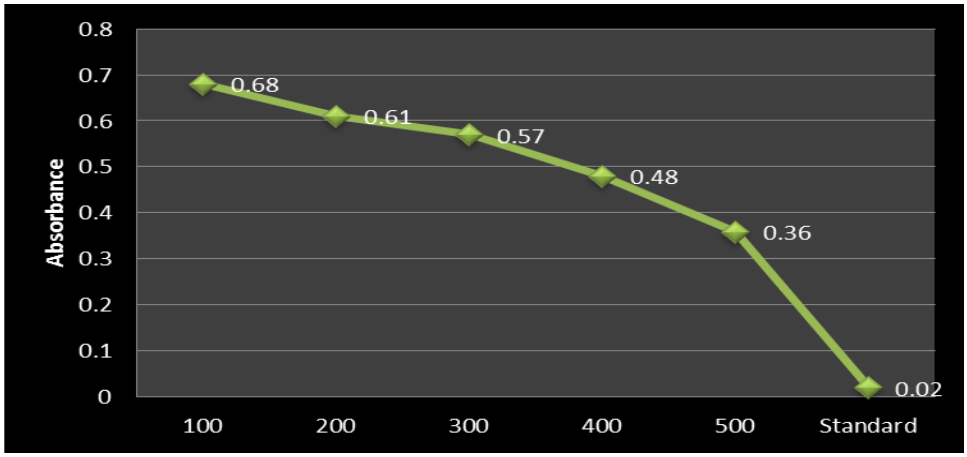
Absorbance Range of test and standard at Trial 1



Absorbance Range of test and standard at Trial 2



Absorbance Range of test and standard at Trial 3



FINAL RESULT

Concentration in µg/ml	Absorbance
Control	0.83 ± 0.01
PKM 100	0.63 ± 0.05
PKM 200	0.56 ± 0.05
PKM 300	0.48 ± 0.07
PKM 400	0.39 ± 0.08
PKM 500	0.30 ± 0.05
Diclofenac sodium (100 µg)	0.017 ± 0.003

Each value represents the mean ± SD. N=3

Concentration in µg/ml	Percentage Inhibition of Protein Denaturation
OK 100	7.823 ± 3.964
OK 200	16.2 ± 4.058
OK 300	25.81 ± 6.67
OK 400	36.99 ± 8.189
OK 500	46.93 ± 4.164
Diclofenac sodium (100 µg)	81.5 ± 1.087

Each value represents the mean ± SD. N=3

Result Analysis

The result obtained from the present clearly indicates that the test drug OK was effective in inhibiting heat induced albumin denaturation. Maximum percentage inhibition of about 46.93 % was observed at 500 μg/ml when compare to that of the Diclofenac sodium, a standard anti-inflammatory agent with the maximum inhibition 81.5 % at the concentration of 100 μg/ml.

Conclusion

From the result of the study it was concluded that the test drug OK possess Convincing anti-inflammatory property in protein denaturation assay.

Reference

1. G.Leelaprakash, S.Mohan Dass. In-vitro anti-inflammatory activity of methanol extract of enicostemma axillare. Int. J. Drug Dev. & Res., 2011, 3 (3): 189-196.
2. M. V. Anoop, A. R. Bindu . In-vitro Anti-inflammatory Activity Studies on Syzygium zeylanicum (L.) DC Leaves. International Journal of Pharma Research & Review, August 2015; 4(8):18-27.

Purpose: Anti- Microbial Profiling

Project Id: NRS/AS/0021/01/2017

Total Sample: 01

Sample ID: **OK**

Institute: Govt Siddha Medical College, Chennai

Disc-diffusion method:

The antibacterial activities of the sample OK were carried out by disc diffusion method. The concentrations of the test compounds were used at the concentration of 100, 200, 300 µg. The target microorganisms were cultured in Mueller–Hinton broth (MHB). After 24 h the suspensions were adjusted to standard sub culture dilution. The Petri dishes containing Muller Hinton Agar (MHA) medium were cultured with diluted bacterial strain. Disc made of Whatman No.1, diameter 6 mm was pre-sterilized and was maintained in aseptic chamber. Each concentration was injected to the sterile disc papers. Then the prepared discs were placed on the culture medium. Standard drug Ciprofloxacin (5µg) was used as a positive reference standard to determine the sensitivity of each microbial species tested. Then the inoculated plates were incubated at 37^{o} C for 24 h . The diameter of the clear zone around the disc was measured and expressed in millimeters as its anti-microbial property. The results were depicted in **Table.**

Organisms used for Anti-Bacterial Activity

s.no	organisms	Type
7.	***Staphylococcus aureus***	**Gram-positive**
8.	***Streptococcus pyogenes***	**Gram-positive**
9.	***Klebsiella pneumonia***	**Gram-negative**

Zone of Inhibition data of Anti-bacterial activity

Sample Code	Klebsiella pneumonia			Streptococcus pyogenes			Staphylococcus aureus		
Concentraion	100 µg	200 µg	300 µg	100 µg	200 µg	300 µg	100 µg	200 µg	300 µg
OK	-	-	-	-	-	-	-	-	-
Ciprofloxacin (5µg)	20			28			22		

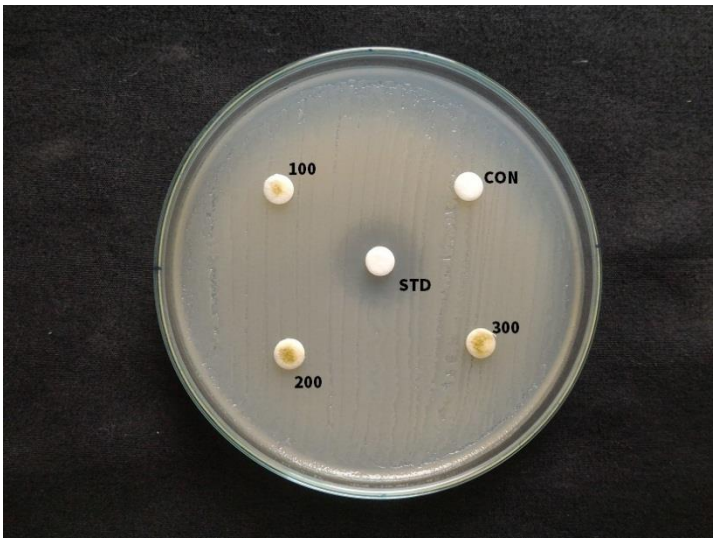
- = Not active

Conclusion

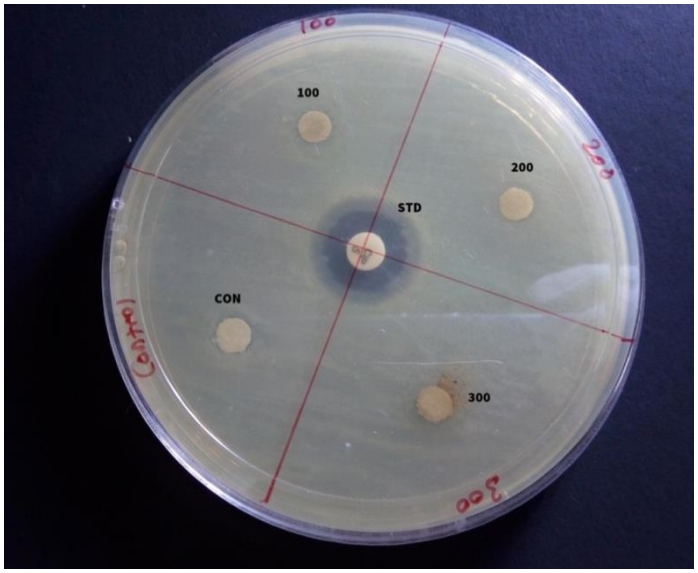
From the results of the present study it was concluded that the sample OK was not effective against any of the tested organism

Anti-Bacterial Evaluation of OK

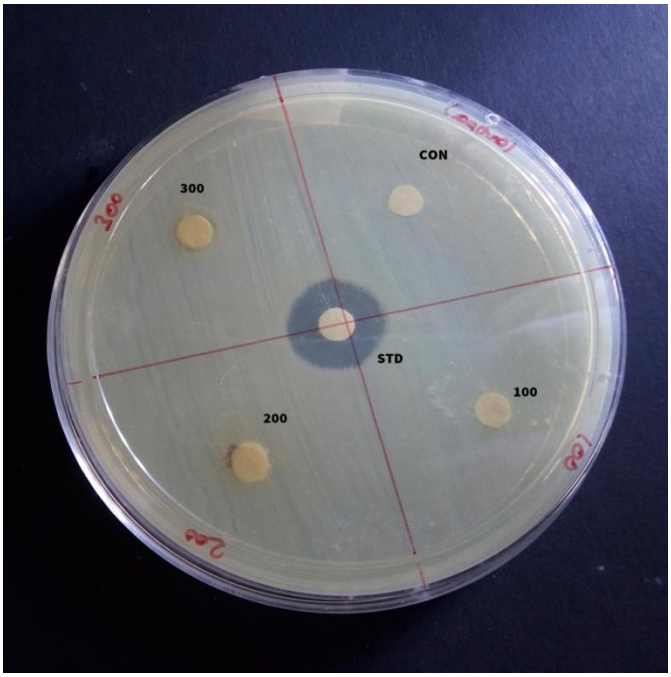
Anti- Microbial Effect of OK against ***Klebsiella pneumonia***



Anti- Microbial Effect of OK against ***Staphylococcus aureus***



Anti- Microbial Effect of OK ***Streptococcus pyogenes***



BIO-STATISTIC ANALYSIS

BIO STATICAL ANALYSIS

Treatment for Neer Kana Mantham(Acute Naso Pharyngitis):

The most popular non parametric statistical tool ,namely, McNemer Test analysis has been employed to analyze the effectiveness with the help of hypothesis

S.NO	Clinical Features	Before Treatment	After Treatment
		n%	n%
1	Cough	40(100)	2(5)*
2	Running Nose	40(100)	3(7.5)**
3	Fever	11(27.5)	1(2.5)***
4	Malaise	4(10)	1(2.5)****
5	Diarrhoea	0(0)	0(0)

Mcnemar's test : C.I:95% * P**<0.0001 ***P=0.0020 ****P<0.2500

Software: spss 17.6 version

Number of cases:40

Inference:

Since the p value is significant in all signs and symptoms. So there is significant reducing of signs and symptoms among the patients for the treatment of Neer kana maantham (Acute Naso pharyngitis). Hence it is concluded that the treatment was effective and **significant**

FORMS

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"OMA KUDINEER"** IN THE TREATMENT OF **"NEER KANA MAANTHAM'' (ACUTE NASO PHARYNGITIS) IN CHILDREN.**

FORM l - SCREENING AND SELECTION PROFORMA

1.OP NO: .....

2. NAME: …….

3. AGE: …… 4.GENDER: …….....

5. F.OCCUPATION: …….. 6.F.INCOME: ……

7. ADDRESS: ……

……

……

8. CONTACT NO: ……

INCLUSION CRITERIA:

Age : 2-12 Yrs

1) Cough Yes / No

2) Running nose Yes/No

3) Fever Yes/No

4) Malaise Yes/No

5) Diarrhoea Yes/No

6) Patients who are willing to undergo Laboratory investigation. Yes/No

7) Patients who are willing to sign the informed consent stating that she will conscientiously stick to the treatment during 48days but can opt out of the trial of her own conscious discretion. Yes / No

I will include patient having atleast 2 to 4 symptoms between 2 and 6

EXCLUSION CRITERIA

(Clinical history)

History of bronchitis

History of bronchial asthma

Severe diarrhoea

ADMITTED TO TRIAL:

YES **NO**

If yes, **OPD/IPD**

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

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CLINICAL STUDY ON '**OMA KUDINEER"** IN THE TREATMENT OF **"NEER KANA MAANTHAM'' (ACUTE NASO PHARYNGITIS IN CHILDREN)**

FORM lI -HISTORY TAKING PROFORMA

1. SERIAL NO OF THE CASE: …….

2.OP/IP NO: .....

3. NAME: ……

4. AGE: …….

5. GENDER: ……..

5.F. OCCUPATION: ……

6.F. INCOME: ……..

7.COMPLAINTS&DURATION:

8.PERSONAL HISTORY:

9. HISTORY OF PREVIOUS ILLNESS

10. BIRTH HISTORY

11. DIETARY HABIT:

1.Vegetarian

2.Non-vegetarian

12. FAMILY HISTORY:

Whether this problem runs in family?

1. Yes 2.No

If yes, mention the relationship of affected person(s) ----------

History of previous investigations if any ----------

Date:

Station

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

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CLINICAL STUDY ONOMA KUDINEER'" IN THE TREATMENT OF

"NEER KANA MAANTHAM (ACUTE NASO PHARYNGITIS)IN CHILDREN

FORM III ASSESSMENT PROFORMA

1. SERIAL NO: ……

2.OP / IP NO: .....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

GENERAL EXAMINATION:

Height (cms) : …….

Weight (kg) : …….

Temperature(°F) : …….

Pulse rate(/min) : …….

Heart rate(/min) : …….

Respiratory rate(/min) : …….

Blood pressure(mm/Hg) : …….

	Present	**Absent**
Pallor		
Jaundice		
Cyanosis		
Lymphadenopathy		
Pedal edema		

Clubbing

Jugular vein pulsation

SYSTEMIC EXAMINATION

CardioVascular System : …….

Respiratory system : …….

Gastro-intestinal system : …….

Central Nervous System : …….

Urogenital system : …….

Endocrine System : …….

SIDDHA SYSTEM OF EXAMINATIONS:

1. THEGI: [BODY CONSTITUTION]

1. Vatha udal
2. Pitha udal
3. Kaba udal
4. Thontha udal

2. NILAM: [LAND WHERE PATIENT LIVED MOST]

1. Kurinji (Hilly terrain)

2. Mullai (Forest range)

3. Marutham (Plains)

4. Neithal (Coastal belt)

5. Paalai (Arid regions)

3. KAALAM:

1. Kaar kaalam
2. Koothir kaalam
3. Munpani kaalam
4. Pinpani kaalam
5. Ilavenil kaalam
6. Muthuvenil kaalam

4. GUNAM:

1.Sathuvam 2.Raasatham 3.Thaamatham

5. IMPORIGAL (SENSORY ORGANS):

Normal/Affected

Mei - ----------

Vaai ----------

Kann ----------

Mukku ----------

Sevi ----------

6. KANMENDHIRIYAM (MOTOR ORGANS):

Kai ----------

Kal ----------

Vaai ----------

Eruvai ----------

Karuvaai ----------

7. KOSANGAL (SHEATH):

Annamaya kosam ----------

Pranamaya kosam ----------

Manomaya kosam ----------

Vignana maya kosam ----------

Anandamaya kosam ----------

8. UYIR THAATHUKKAL: [THREE HUMORS] (VALI, AZHAL, IYAM)

A) VALI

Pranan –----------

Abanan ----------

Samanan ----------

Uthanan ----------

Vyanan ----------

Naagan ----------

Koorman ----------

Kirukaran ----------

Devathathan ----------

Dhananjayan ----------

B) AZHAL

Analakam ----------

Ranjakam ----------

Sathakam ----------

Prasakam ----------

Alosakam ----------

C) IYAM

Avalambagam ----------

Kilethagam ----------

Pothagam ----------

Tharpagam ----------

Santhigam ----------

9. SEVEN UDAL THATHUKKAL: (SEVEN SOMATIC COMPONENTS)

Saram ----------

Senneer ----------

Oon ----------

Koluppu ----------

Enbu ----------

Moolai ----------

Sronitham ----------

10. ENVAGAI THERVU:

I. NAADI: [PULSE PERCEPTION]

II. SPARISAM: [PALPATION]

III. NAA: [TONGUE]

IV.NIRAM: [COMPLEXION]

1. Vadham
2. Pitham
3. Kabam

V.MOZHI: [VOICE]

1. High Pitched

2. Low Pitched
3. Medium Pitched

VI.VIZHI: [EYES]

VII. MALAM: [BOWEL HABITS / STOOLS]

Niram

Irugal

Ilagal

Others

VIII. MOOTHIRAM [URINE EXAMINATION]

NEERKKURI:

Niram

Manam

Edai

Nurai

Enjal

NEIKKURI

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

POST- GRADUATE DEPARTMENT OF KUZHANTHAI MARUTHUVAM

CLINICAL STUDY ON **"OMA KUDINEER""** IN THE TREATMENT OF

"NEER KANA MAANTHAM'' (ACUTE NASO PHARYNGITIS IN CHILDREN)

FORM IV : LABORATORY INVESTIGATIONS PROFORMA

1. SERIAL NO OF THE CASE: ……

2.OP / IP NO: .....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

A) BLOOD INVESTIGATIONS:

BLOOD INVESTIGATIONS		**BEFORE TREATMENT**	**AFTER TREATMENT**
Hb (gm/dL)			
Absolute eosinophil count (Cells/ul)			
ESR (mm)	**½ hr.**		
	1 hr.		
T.WBC (Cells / Cu.mm)			
Differential Count (%)	**Polymorphs**		
	Lymphocytes		
	Monocytes		
	Eosinophils		
	Basophils		

INVESTIGATIONS		BEFORE TREATMENT	AFTER TREATMENT
Motion	Ova		
	Cyst		
	Occult blood		

B) URINE INVESTIGATIONS:

URINE INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar		
Deposits		

Date:

Station:

Signature of the Guide

Signature of the Investigator

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"OMA KUDINEER"** IN THE TREATMENT OF **''NEER KANA MAANTHAM'' (ACUTE NASO PHARYNGITIS IN CHILDREN)**

FORM V: INFORMED CONSENT FORM

*"**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.***

***I consent voluntarily to participate my chid in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my chid further medical care**".*

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant:

In case of illiterate participant

*"**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely**."*

Date:

Signature of a witness Left thumb Impression of the Participant

(Selected by the participant bearing no connection with the survey team)

Date:

Station:

Signature of participant:

Signature of the Guide: **Signature of the Investigator:**

GOVERNMENT SIDDHA MEDICAL COLLEGE, CHENNAI

CLINICAL STUDY ON **"OMA KUDINEER"** IN THE TREATMENT OF

NEER KANA MAANTHAM (ACUTE NASO PHARYNGITIS IN CHILDREN)

FORM VI - WITHDRAWAL FORM

SI NO:

OP / IP NO:

NAME:

AGE / GENDER :

DATE OF TRIAL COMMENCEMENT:

DATE OF WITHDRAWAL FROM TRIAL:

REASONS FOR WITHDRAWAL:

- Long absence at reporting : Yes/ No
- Irregular treatment: Yes/ No
- Shift of locality : Yes/No
- Increase in severity of symptoms: Yes/No
- Development of severe adverse drug reactions: Yes/No

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"OMA KUDINEER"** IN THE TREATMENT OF

"NEER KANA MAANTHAM (ACUTE NASO PHARYNGITIS IN CHILDREN)

FORM VII – PATIENT INFORMATION SHEET

Name of Co- Investigator: D.S.LAVANYA Name **of the college:**

Govt.Siddha Medical College

Arumbakkam

Chennai-106.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I,D.S.LAVANYA studying M.D (Siddha) at Govt.Siddha Medical College, Chennai, is doing a clinical trial on '' **OMA KUDINEER"** IN THE TREATMENT OF

NEER KANA MAANTHAM (ACUTE NASO PHARYNGITIS IN CHILDREN)

. It is becoming a most common disease, occurring throughout the world. In this regard, I am in need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine‘‘OMA KUDINEER’’ for-7 days

The information I am collecting in this study will remain between you and the Co- investigator (myself). I will ask you few questions through a questionnaire. I will not write your name on this form. I will use a code instead.

The questionnaire will take approximately 20 minutes of your time.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact D.S.Lavanya, PG Scholar cum Co-investigator of this study, attached to Govt. Siddha Medical College, Chennai-106. You can also contact the Member-secretary of Ethics committee, Govt.Siddha Medical College, Chennai.

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"OMA KUDINEER"** IN THE TREATMENT OF

"NEER KANA MAANTHAM (ACUTE NASO PHARYNGITIS IN CHILDREN

FORM X - ADVERSE REACTION REPORTING FORM

SERIAL NO:

OP/IP NO:

NAME: **AGE:** **GENDER:**

DATE OF TRIAL COMMENCEMENT:

DATE OF OCCURRENCE OF THE ADVERSE REACTION: **TIME:**

DESCRIPTION OF ADVERSE REACTION:

MANAGEMENT:

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVT SIDDHA MEDICAL COLLEGE AND HOSPITAL CHENNAI

Branch -IV KUZHANTHAI MARUTHUVAM

PROFORMA OF CASE SHEET FOR NEER KANA MANTHAM

OP. No : **Nationality :**

Name : **Religion :**

Age : **Date of Admission :**

Sex : **Date of Discharge :**

Address : **Diagnosis :**

Informant : **Medical Officer :**

1. Complaints and duration :

2. History of present illness :

3. History of Past illness :

4. Antenatal history :

5. Birth history :

6. Neonatal history :

7. Developmental history :

8. Nutritional history :

9. Immunization history :

10. Family history :

11. Socio economic status :

General examination

1. Appearance and posture :

2. Nutritional status :

3. Anaemia :

4. Cyanosis :

5. Clubbing :

6. Jaundice :

7. Lymphadenopathy :

8. Abdominal distension :

9. Pedal oedema :

Vital Signs

1. Temperature :

2. Pulse rate :

3. Respiratory rate :

4. Heart rate :

5. Blood pressure :

Anthropometry

a. Height :

b. Weight :

c .Chest circumference :

SIDDHA ASPECT

Nilam

1. Kurinji :

2. Mullai :

3. Marutham :

4. Neithal :

5. Paalai :

Paruvakaalam

1. Kaar :

2. Koothir :

3. Munpani :

4. Pinpani :

5. Elavenil :

6. Muthuvenil :

Poripulangal

1. Mei :

2. Vai :

3. Kan :

4. Mooku :

5. Sevi :

Kanmenthiriyam

1. Kai :

2. Kaal :

3. Vaai :

4. Eruvai :

5. Karuvai :

Uyir thathukkal

Vadham

1. Praanan :

2. Abaanan :

3. Viyaanan :

4. Uthaanan :

5. Samaanan :

6. Naagan :

7. Koorman :

8. Kirukaran :

9. Devathathan :

10. Dhananjeyan :

Pitham

1. Analpitham :

2. Ranjagam :

3. Saadhagam :

4. Praasagam :

5. Aalosagam :

Kabam

1. Avalambagam :

2. Kiletham :

3. Pothagam :

4. Tharpagam :

5. Santhigam :

Udar kattugal

1. Saaram :

2. Senneer :

3. Oonn :

4. Kozhuppu :

5. Enbu :

6. Moolai :

7. Sukkilam / Suronitham**:**

Envagai thervugal

1. Naadi :

2. Sparisam :

3. Naa :

4. Niram :

5. Mozhi :

6. Vizhi :

7. Malam :

8. Moothiram :

MODERN ASPECTS

1. Respiratory System :

2. Cardiovascular system :

3. Gastro intestinal system :

4. Central nervous system :

5. Excretory system **:**

Laboratory investigations

Blood

TC :

DC :

ESR :

1/2 hr :

1 hr :

Hb%

Urine

Albumin :

Sugar :

Deposits :

Investigation - Siddha aspect

1. Neerkuri

Niram :

Edai :

Manam :

Nurai :

Enjal :

2. Neikuri

3.Daily progress

Date	**Symptoms**	**Medicine**

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106

அறிஞர் அண்ணா மருத்துவமனை, சென்னை.

நீர்க்கண மாந்தம் நோய்க்கான் சித்த மருத்தின் (**ஓமக்குடிநீர்**) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான் தகவல் படிவம். ஒப்புதல் படிவம் ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இந்த ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

நோயாளியின் பெற்றோர் ஒப்புதல் படிவம்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும், தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் எனது குழந்தையின் இந்த மருத்துவ ஆய்வின் போது, காரணம் எதுவும் கூறாமல், எப்பொழுத்ய வேண்டுமானாலும் இந்த ஆய்விலிருந்து எனது குழந்தையின் விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன். நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு நோய்க்கான ஓமக்குடிநீர் மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

தேதி: சாட்சிக்காரர் கையொப்பம்:

இடம்: பெயர்:

உறவுமுறை

துறைத்தலைவர் கையொப்பம்: ஆராய்ச்சியாளர் கையொப்பம்:

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106
அறிஞர் அண்ணா மருத்துவமனை, சென்னை.

நீர்க்கண மாந்தம் நோய்க்கான் சித்த மருத்தின் (ஓமக்குடிநீர்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான் தகவல் படிவம்.

ஆராய்ச்சியாளர் பெயர் : தா.ச.லாவண்யா
நிறுவனத்தின் பெயர் : அரசு சித்த மருத்துவக் கல்லூரி
அரும்பாக்கம், சென்னை-106.

அரசு சித்த மருத்துவக் கல்லூரியில் பட்ட மேற்படிப்பு பயின்று வரும் நான் மருத்துவர். தாச.லாவண்யா. நீர்க்கண மாந்தம் என்னும் நோயில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

இந்த நோய் கிருமிகளினால் எற்படுகின்றன. இது பரவக் கூடியநோய்.

இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளைக் கேட்கவும், தேவையான் ஆய்வகப் பரிசோதனைக்கு தங்களை உட்படுத்தவும் உள்ளேன்.

இந்த ஆராய்ச்சிக்கு தங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக ஓமக்குடிநீர் 2வேளை(காலை, மாலை) உணவுக்கு பின் 7 நாட்கள் உட்கொள்ள வேண்டும்.

இந்த மருந்து சிறப்பாக நீர்க்கண மாந்தம் நோய்க்காஅங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது.

இந்த ஆராய்ச்சியில் தங்களை அனுமதித்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் ஆராய்ச்சியில் இருந்து விலகிக் கொள்ள உரிமை உள்ளது.

இந்த ஆராய்ச்சி சம்பந்தமாக நோயின் தன்மை பற்றியும் மற்ற விபரங்களுக்கும் ஆராய்ச்சியாளர் மருத்துவர் : தா.ச.லாவண்யா (பட்ட மேற் படிப்பாளர் குழந்தை மருத்துவ துறை) அவர்களை எந்த நேரத்திலும் தொடர்பு கொள்ளலாஅம் கைப்பேசி எண் : 9176126948

மேலும் இந்த ஆராய்ச்சிக்கு தக்க அனுமதிச் சான்று(IEC) பெறப்பட்டுள்ளது

இந்த மருந்து முற்றிலும் பாதுகாப்பான மூலிகை பொருட்களைக் கொண்டு தயாரிக்கப்பட்டுள்ளது. பக்க விளைவுகளை ஏற்படுத்தாது.

மேலும் உணவு முறையில் மருத்துவரால் கூறப்படும் பத்தியம் காக்குமாறு அறிவுறுத்த படுகிறது.

இது சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன்.

இதில் பயணப்படி முதலிய எந்த உதவித் தொகையும் வழங்கப் பட மாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் அறிஞர் அண்ணா மருத்துவமனையில், தக்க சிகிச்சை அளிக்கப்படும்.

CASE SHEET
PROFPRMA

Department of PG Kuzhanthai Maruthuvam			
Dissertation study on NEER KANA MAANTHAM			
Guide:Dr.S.Gandhimathi MD(s)		Investigator:Dr.D.S.Lavanya PG Scholar	
Aringar Anna hospital OPD,Chennai-106			
NAME		OP.NO	
AGE/SEX		DATE	
CONTACT NO		DIAGNOSIS	
ADDRESS			

COMPLAINTS AND DURATION					
a)cough	☐ Yes	☐ No			
b)Runningnose	☐ Yes	☐ No			
c)Fever	☐ Yes	☐ No			
d)Malaise	☐ Yes	☐ No			
e)Diarrhoea	☐ Yes	☐ No			
Other complaints					

PAST HISTORY					
FAMILIAL HISTORY					
MODE OF ONSET	☐ Acute	☐ Chronic			
FOOD HABITS	☐ Veg	☐ Non-veg			
ECONOMIC STATUS	☐ Poor	☐ middle	☐ rich		

ON EXAMINATION	
Height	
weight	
CVS	
RS	
Others	

Department of PG Kuzhanthai Maruthuvam	
Dissertation study on NEER KANA MAANTHAM with evaluation of OMA KUDINEER	
Guide:Dr.S.Gandhimathi ,MD(s)	**Investigaor:Dr.D.S.Lavanya ,PG scholar**
Aringar Anna hospital OPD,Chennai-106	

ENVAGAI THERVU	
Naa	
Niram	
Mozhi	
Vizhi	
Sparism	
Malam	
Moothiram	
Naadi	

INVESTIGATION			
Before treatment		**After treatment**	
Blood		**Blood**	
TC		**TC**	
DC		**DC**	
ESR		**ESR**	
HB		**HB**	
Others		**Others**	
MEDICINE			
PROGNOSIS			

WEEKS/DATE	COUGH	RUNNING NOSE	FEVER	MALAISE	DIARRHOEA	M.OSIGN

RECURRENCE

RESULT

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